Annex

3 Public Health Reasons/ Administrative Guidelines

Chapter 1 Purpose and Definitions

Applicability and Terms Defined

1-201.10 Statement of Application and Listing of Terms.

(B) *Terms Defined*

The individual definitions in Chapter 1 are not numbered, consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Food Code. The intent of the definitions to be binding in terms of the application and interpretation of the Code is clearly stated in Chapter 1.

Accredited Program.

Refer to the definition for Accredited Program in ¶1-201.10 (B)(3).

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, 2792 Miramar Lane, Lincoln, CA 95648 and found at http://www.foodprotect.org/

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.

Egg.

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich.

Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S.* Enteritidis within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a time/temperature control for safety food subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item “Alligator Eggs” is sometimes made of alligator egg, but other times is simply a fanciful name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp’s Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Food establishment and food processing plant.

Food Establishment and a food processing plant located within the same premises of a food establishment

Some food businesses perform operations that provide food directly to consumers as a “Food Establishment,” and also supply food to other business entities as a “Food Processing Plant.” Within such a business, those operations that provide food directly to consumers only should be considered part of a “Food Establishment” for the purposes of applying the Food Code while those operations that supply food to other business entities may be subject to other rules and regulations that apply to “Food Processing Plants”. It is essential that the permit holder and persons in charge be aware that regulatory requirements and the appropriate operational practices for “Food Establishments” may differ from those for “Food Processing Plants.”

Some facilities and functions may be subject to different regulatory requirements depending on whether that facility or function is regulated as a “Food Establishment” or as a “Food Processing Plant”, or both. Those facilities and functions within a business that are shared by both the “Food Establishment” and “Food Processing Plant” operations, e.g., refrigeration units, dressing room and toilet facilities, food equipment, water and waste systems, pest control, might be subject to similar regulatory requirements. The Food Code is intended to apply to “food establishments”.

Packaged.

The definition of “packaged” was revised in (2) to clarify when foods packaged at retail need not be labeled.

Refer to Public Health Reasons for Food Labels §3-602.11.

Time/Temperature Control for Safety Food

Time Temperature Control for Safety Food (TCS) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

The definition of TCS food takes into consideration pH, a_w, pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a TCS food.

A well designed inoculation study or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or

- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B in paragraph 1-201.10(B) of the definition for "time/temperature control for safety food" in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
    - If the answer is No, no further action is required. The decision tree later in this Annex is not needed to determine if the item is a TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in paragraph 1-201.10(B)?
- Does a product history with sound scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as ultra high temperature (UHT) creamers or shelf-stable canned goods?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

A food designated as product assessment required (PA), in either table should be considered TCS Food until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered TCS until inoculation studies or some other acceptable evidence shows that the food is a TCS food or not. The Food Code requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

The Food Code definition designates certain raw plant foods as TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat-treated),. fresh sprouts (pH > 6.5, $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a variance is required under ¶ 3-502.11(C). A HACCP plan is required whether the food is a TCS food as in subparagraph 3-502.11 (C)(1) or not a TCS food, as in subparagraph 3-502.11(C)(2). A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the variance request with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm

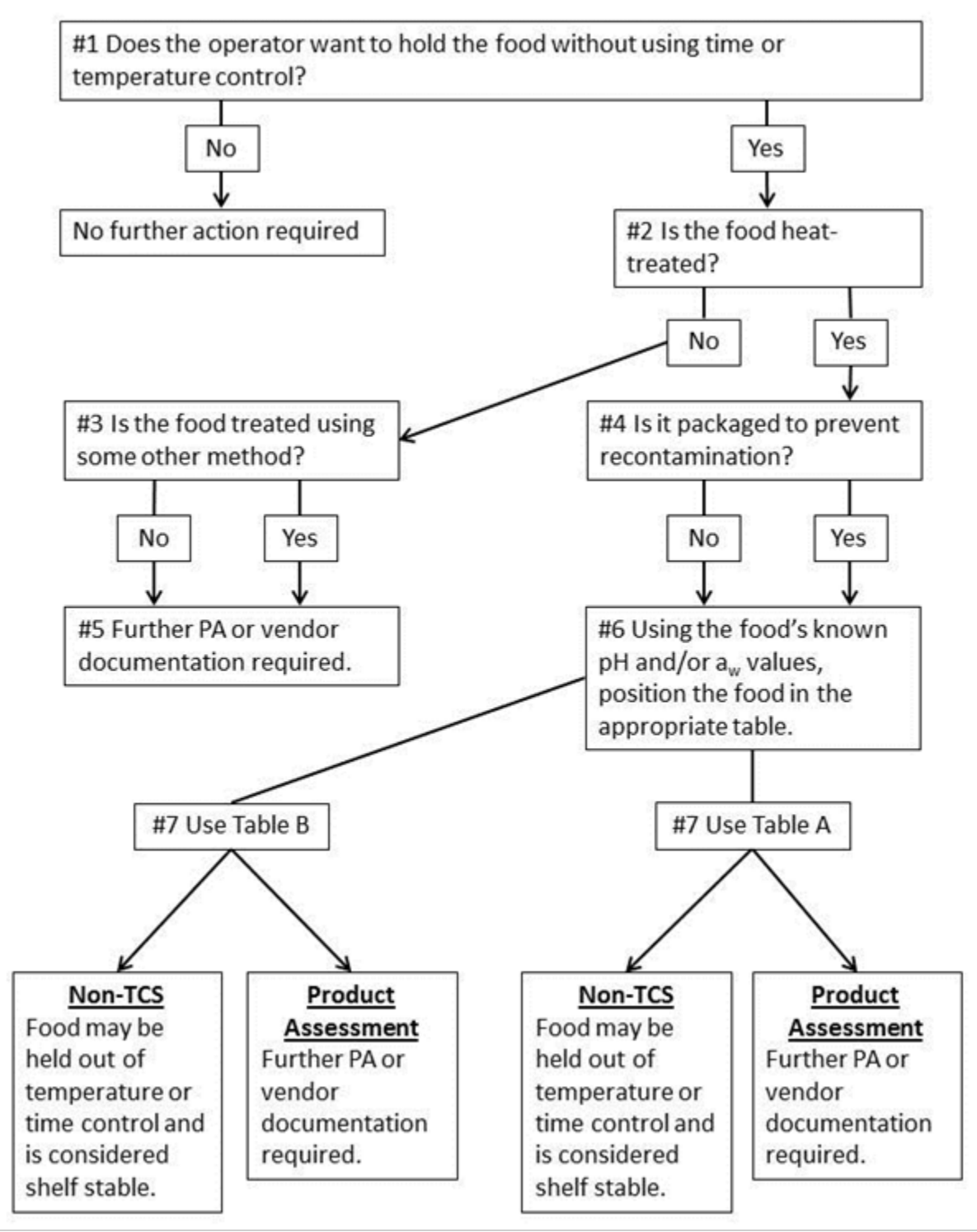
Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
    a. No – Continue holding the food at ≤5°C(41°F) or ≥57°C(135°F) for safety and/or quality.
    b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
    a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
    b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
    a. No –The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
    b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
    a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
    b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
    a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.

b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.

6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
    a. Choose the column under "pH values" that contains the pH value of the food in question.
    b. Choose the row under "a_w values" that contains the a_w value of the food in question.
    c. Note where the row and column intersect to identify whether the food is "non-TCS food" and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.
7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-TCS or needs further product assessment (PA).

1-201.10(B) Decision Tree #1 – Using pH, a_w, or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



1-201.10(B) – Table A and Table B

Table A. Interaction of pH and a_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

a_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

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.

In cases where a food establishment has several departments on the premises (e.g., a grocery store with deli, seafood, and produce departments) and the regulatory authority has permitted those departments individually as separate food establishments, it may be unnecessary from a food safety standpoint to staff each department with a separate Person in Charge during periods when food is not being prepared, packaged or served. While activities such as moving food products from a refrigerated display case to the walk-in refrigerator, cleaning the floors, or doing inventory when the department is not busy, do take place during these times, a designated Person in Charge for multiple departments or the entire facility can oversee these operations and be ready to take corrective actions if necessary.

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 no bare hand contact with ready-to-eat (RTE) food is a Code requirement.

2-102.12 Certified Food Protection Manager

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the risk factors that impact the safety of the food they sell or serve. Food protection managers have an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not.

FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types.

There are a number of state and local agencies that currently mandate food protection manager certification. It is appropriate for State and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one.

Factors to consider when establishing such criteria include:

- the size and scope of the operation;
- the hours of operation;,
- the types of foods sold or served;
- the extent to which food is prepared on site;
- the number of staff,
- type of population served, e.g. highly susceptible or not; and
- the number of meals served.

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been 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 administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its ***Standards for Accreditation of Food Protection Manager Certification Programs*** found at: http://www.foodprotect.org/food-protection-manager-certification/. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

> "The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.
>
> The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.
>
> Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.
>
> FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National

Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited (http://www.ansi.org/) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***.*

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.**

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system."

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

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service

*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to: https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4

** Accredited program does not refer to training functions or educational programs.

personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, time/temperature control for safety foods must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer.

To minimize the potential for access to the food establishment and the food by an unauthorized person, precautions should be applied overall to the food establishment and especially when access to the facility is made under key access deliveries. Additional information on food defense can be viewed at: http://www.fda.gov/Food/FoodDefense/default.htm

An important duty of the Person in Charge is to make sure that any required temperatures are achieved or maintained when foods are cooked, cooled or held in a food establishment. By making it a duty of the Person in Charge to ensure that employees are monitoring food temperatures to verify the critical temperature limits, the likelihood of temperature abuse is reduced. This includes oversight of temperature monitoring to ensure: 1) that animal foods are being cooked to the required minimum temperatures to prevent the survival of pathogens that may be present (2-103.11(G)); 2) that cooked foods are being cooled rapidly to ensure that the growth of bacterial pathogens and toxin production is prevented (2-103.11(H)); and 3) that foods that require temperature control for safety are being held at temperatures that adequately prevent pathogen growth and toxin production (new 2-103.11(I)).

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food

Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (M) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.

Paragraph (N) "EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Paragraph (O) emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

- The ability to provide documentation that all food employees and conditional employees are informed of their responsibility to report to management, such as completion of Form 1-B, "Conditional Employees or Food Employees Reporting Agreement" in Annex 7 or other similar state or local forms containing the same information;

- Presenting evidence such as curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required for reporting in Form 1-B;

- Implementation of an employee health policy that includes a system of employee notification using a combination of training, signs, pocket cards or other means to convey all the required information (Refer to Annex 3, 2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201, for further guidance);

- Other methods that satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to the PIC information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶2-201.11 (A)

In various places throughout the Code, it is specified that either written operating procedures or operational plans be developed. The link between management responsibility for developing and implementing the procedures or plans is now established as a new duty for the Person in Charge (PIC). This new provision does not establish new requirements in the development of plans or procedures; rather it emphasizes the importance of the role the PIC plays in ensuring active managerial control of the food establishment with the development and implementation of plans and/or procedures as specified in this Code. Examples of Code provisions that call for the development of plans or procedures can be found in: §2-501.11, ¶¶3-301.11(D) and 3-401.14 (F), §§ 3-501.19, and 5-205.14. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. There are many tools that industry can use to develop an effective system to achieve active managerial control of foodborne illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the development and implementation of written procedures or plans.

(Also refer to Annex 4 – Management of Food Safety Practices (1) (D) for further information).

2-2 Employee Health

Overall goals

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food employees into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food employees, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food employees through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of

symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting – with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, ***E. coli*** O157:H7 or other Shiga toxin-producing ***Escherichia coli*** (STEC), ***Shigella*** spp. infection, or nontyphoidal *Salmonella*.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, ***E. coli*** O157:H7 or other STEC, and ***Shigella*** spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees). Dark urine and light colored stool may be an indicator of a hepatitis A infection but may go unreported.

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to

spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The Food Code provides restriction guidelines for food employees working in facilities serving a HSP. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees working in facilities not serving a HSP pay particular attention to personal hygiene and report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food employee will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the six important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens posted on CDC's website, and from the Control of Communicable Diseases Manual, 19th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2008.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee

Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶3-301.11(E)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 6 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

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 has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. The questions or examinations are designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

Reporting Symptoms:

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. 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. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness. The symptoms of vomiting, diarrhea, or jaundice serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes. Streptococcus pyogenes* causes a common infection otherwise known as “streptococcal sore throat” or “strep throat.” Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food employees hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

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 a food employee has an infected cut and bandages it and 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.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has Typhoid fever (caused by *Salmonella* Typhi), or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA

disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or

- all reasonable accommodations would pose an undue hardship on the employer's business; and

- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with Typhoid fever (caused by *Salmonella* Typhi). The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting Typhoid fever (caused by *Salmonella* Typhi) through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.[1]

Example 2: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and

[1] Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease through food, or any such accommodation would be an undue hardship to the business.

- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

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 Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. See the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that 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 their specific history of exposure, 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.

Section 103 (d) of the Americans with Disabilities Act of 1990, Public Law 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The CDC published on its website in November 2012 a list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens. See the list at: https://www.cdc.gov/foodsafety/pdfs/ada2017_transmittedbyfood_final.pdf

The final list has been reviewed in light of new information and has been revised as set forth below.

Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle

food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine or jaundice. The failure of food-handlers to wash hands in certain situations (such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage), wear clean disposable gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens.

Some pathogens usually cause disease when food is intrinsically contaminated or cross-contaminated during production, processing or transportation, but may also be contaminated when prepared by infected persons. Bacterial pathogens in this category often cause disease after bacteria have multiplied in food after it has been kept at improper temperatures permitting their multiplication to an infectious dose. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting these pathogens.

The following represent both types of pathogens that may be transmitted by an infected food handler:

Astroviruses
Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Cryptosporidium species
Entamoeba histolytica
Enterohemorrhagic *E. coli*
Enterotoxigenic *E. coli*
Giardia intestinalis
Hepatitis A virus
Nontyphoidal *Salmonella*
Noroviruses
Rotaviruses
Salmonella Typhi*
Sapoviruses
Shigella species
Staphylococcus aureus
Streptococcus pyogenes
Taenia solium - cysticercosis
Vibrio cholera
Yersinia enterocolitica

* 1. Kauffmann-White scheme for designation of Salmonella serotypes

The 6 Listed Pathogens:

The CDC has designated the 6 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 19th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, 2nd Edition, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 6 listed pathogens.

NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are small (27-40 nm), round structured, single-stranded RNA, nonenveloped viruses. They are a genetically diverse group classified into at least five genogroups, designated GI-GV, which are further sub-divided into at least 35 genotypes. Noroviruses are recognized as the most common cause of epidemic and sporadic gastroenteritis across all age groups worldwide.

Transmission of norovirus occurs primarily through the fecal-oral route, including direct person-to-person contact and indirect transmission through contaminated food, water, or environmental surfaces. Vomitus-oral transmission can also occur through aerosolization followed by direct ingestion or environmental contamination.

Noroviruses are the leading cause of foodborne illness in the United States. Food handler contact with raw or other ready-to-eat foods is the most common scenario resulting in foodborne norovirus outbreaks. Norovirus contamination of produce and shellfish can also occur during production. Secondary household transmission is common.

Noroviruses are environmentally stable, able to survive both freezing and heating (although not thorough cooking), are resistant to many common chemical disinfectants, and can persist on surfaces for up to 2 weeks. Proper hand hygiene and exclusion of food employees exhibiting symptoms of norovirus disease (i.e., diarrhea or vomiting) are critical for norovirus control.

Incubation Period: In volunteer studies, the range is 10-50 hours. In foodborne norovirus outbreaks, the median incubation period is 33 hours.

Symptoms and Complications: Acute-onset of vomiting, watery non-bloody diarrhea, abdominal cramps, and nausea, or a combination of these symptoms. Low grade fever and body aches may also be associated. Symptoms typically last 24 to 72 hours. Norovirus disease is usually self-limited without any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. Volunteer

studies have found that as many as 30% of individuals infected with norovirus are asymptomatic. There is no specific treatment for norovirus disease. Supportive therapy consists of oral or intravenous rehydration solutions to replace fluid loss and electrolytes. Previous exposure does not provide long-term immunity; thus, individuals may be repeatedly infected throughout their lifetimes.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 18 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms, peaks 4 days after exposure, and may persist for 3 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined and peak contagiousness is during the acute stage of disease. Peak viral loads in both symptomatic and asymptomatic infections (may be as high as 100 billion viral particles/g feces).

NONTYPHOIDAL *SALMONELLA*

Caused by serotypes ***other than*** *S.* Typhi and *S.* Paratyphi A.

Unlike previous editions of the FDA Food Code, the 2013 edition requires food employees to report a diagnosis of nontyphoidal *Salmonella* (NTS), prompts the person in charge to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from NTS, and where appropriate, approval from the regulatory authority.

Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common bacterial cause of foodborne illness. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Forty-six percent of *Salmonella* outbreaks occurred in restaurant/deli establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). For the period of 2009-2010, the 243 *Salmonella* outbreaks reported to the CDC accounted for 51% of bacterial foodborne disease outbreaks. Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or

cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et. al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e., symptoms and exposures, testing of stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

General Description:
Nontyphoidal *Salmonella* (NTS) *enterica* are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

Salmonella lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with *Salmonella* by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water.

Most infections are thought to be acquired through consumption of contaminated food.

Incubation Period:
Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:
Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:
The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple

outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term “shedding” is used to describe the excretion of *Salmonella* in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

***SALMONELLA* TYPHI**

Salmonella enterica subspecies *enterica* serovar Typhi (commonly *S*. Typhi) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of ***S*. Typhi** in industrialized nations are imported into the country from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

Incubation period: Generally 1 to 3 weeks, but may be as long as 2 months after exposure.

Symptoms and Complications: High fever, from 103° to 104°F; lethargy; gastrointestinal symptoms, including abdominal pains and diarrhea or constipation; headache; achiness; loss of appetite. A rash of flat, rose-colored spots sometimes occurs. Septicemia, with colonization of other tissues and organs; e.g., may lead to endocarditis. Septic arthritis may occur, in which the infection directly affects the joints and may be difficult to treat. Chronic infection of the gallbladder may occur, which may cause the infected person to become a carrier.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with ***S*. Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers.

SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*

E. coli O157:H7 is the most commonly identified serotype of Shiga toxin-producing ***Escherichia coli*** (STEC) as a cause of foodborne illness in the United States. ***E. coli*** O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, ***E. coli*** O157:H7 also readily transmits from person-to-person, so contaminated raw

ingredients and ill food employees both can be sources of foodborne disease. Other STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as ***E. coli*** O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are O26, O111, O103, O45, and O121.

The Food Code definition of STEC covers all ***E. coli*** identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of ***E. coli*** have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). Infections with STEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). [Note: "enterohemorrhagic" (EHEC) is a subset of STEC that has the capacity to both produce Shiga toxin and cause "attaching and effacing" lesions in the intestine.]

Incubation period: Symptoms usually begin 3 to 4 days after exposure, but the time may range from 1 to 9 days.

Symptoms and Complications: Hemorrhagic colitis is characterized by severe cramping (abdominal pain), nausea or vomiting, and diarrhea that initially is watery, but becomes grossly bloody. In some cases, the diarrhea may be extreme, appearing to consist entirely of blood and occurring every 15 to 30 minutes. Fever typically is low-grade or absent. Infections from EHEC may range from asymptomatic to mild diarrhea to severe, life threatening complications (e.g., hemorrhagic colitis, hemolytic uremic syndrome)). About 3% to 7% STEC infections progress to HUS .

Infectivity: The infective dose of E. coli O157:H7 is estimated to be very low, in the range of 10 to 100 cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of STEC in the stool is typically 1 week or less in adults, but can be up to 3 weeks or longer in one-third of infected children.

SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An estimated 300,000 cases of shigellosis occur annually in the U.S. ***Shigella*** spp. consist of 4 species or serogroups, including ***S. flexneri***, ***S. boydii***, ***S. sonnei***, and ***S. dysenteriae***; which all differ in geographical distribution and pathogenicity. ***Shigella*** spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food employees' hands, are common causes of disease transmission. Multidrug-resistant

Shigella (including ***S. dysenteriae* type** 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Eight to 50 hours.

Symptoms and Complications: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxaemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 5-7 days. Infections are also associated with rectal bleeding, drastic dehydration, and convulsions in young children. The fatality rate for ***Shigella dysenteriae*** 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

Infectivity: The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs 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.

HEPATITIS A VIRUS

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild,

unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

HAV Immunization: Immune globulin (IG) can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food employee with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions.

Hepatitis A vaccination of food employee has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28-30 days (range 15-50 days).

Symptoms and Complications: Illness usually begins with symptoms such as nausea/ vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery, without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

Diagnosis: Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectable within 6 months of illness onset for most persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

Infectivity: The infective dose of HAV is presumed to be low (10 to 100 viral particles), although the exact dose is unknown. The viral particles are excreted in the feces of ill people (symptomatic and asymptomatic) at high densities (10^6 to 10^8/gm) and have

been demonstrated to be excreted at these levels for up to 36 days post-infection. Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

Reporting History of Exposure:

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC, typhoid fever, HAV.

Which employees who report exposure are restricted?

- Employees who work in a food establishment serving a highly susceptible population (HSP) facility, except those employees who are exposed to nontyphoidal *Salmonella* (NTS).

Why don't employees who are exposed to nontyphoidal *Salmonella* (NTS) need to be restricted?

- For those employees who are exposed to nontyphoidal *Salmonella,* exposure alone does not necessitate restriction of the employee based on epidemiologic evidence of no increased risk of employees with only a history of exposure versus employees who were infected and diagnosed.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.

- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.
    - For norovirus, 48 hours after the most recent exposure
    - For ***Shigella*** spp., 3 days after the most recent exposure
    - For ***E. coli*** O157:H7 or other STEC, 3 days after the most recent exposure
    - For typhoid fever (***S*. Typhi**), 14 days after the most recent exposure
    - For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, ***Shigella*** spp., ***E coli*** O157:H7 or other STEC, typhoid fever (***S*. Typhi**) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
    - For norovirus, symptomatic period plus 48 hours
    - For ***Shigella*** spp., symptomatic period plus 3 days
    - For ***E. coli*** O157:H7 or other STEC, symptomatic period plus 3 days
    - For typhoid fever (***S*. Typhi**), symptomatic period plus 14 days
    - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

- Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

2-201.12 Exclusions and Restrictions.[2]

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a noninfectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (***Salmonella* Typhi**) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by norovirus, ***Shigella*** spp., STEC, or nontyphoidal *Salmonella* (NTS), is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

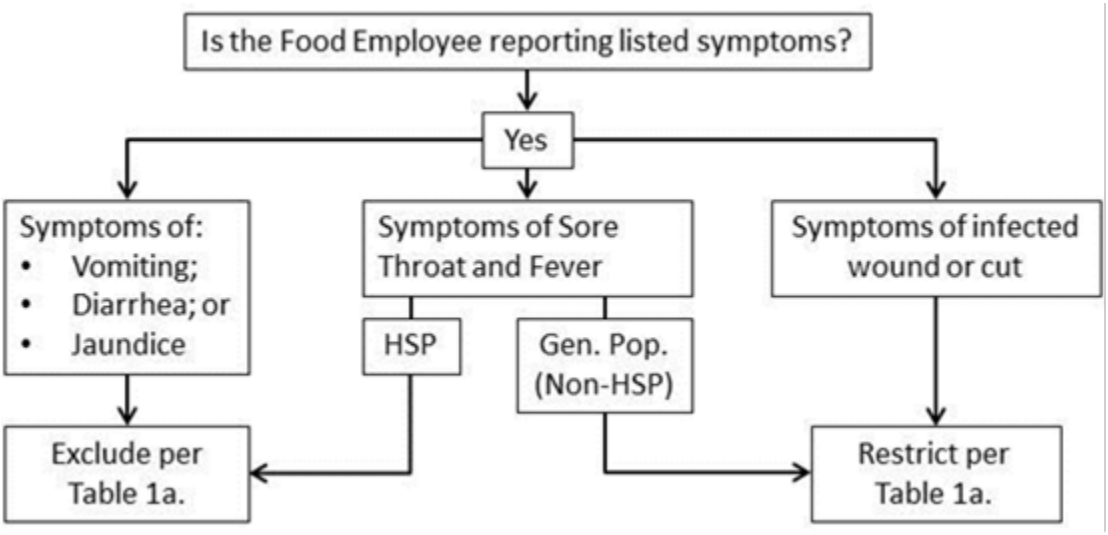
Restriction of food employees infected with NTS after resolution of symptoms has not been a national standard. However, because of the prolonged duration of shedding of

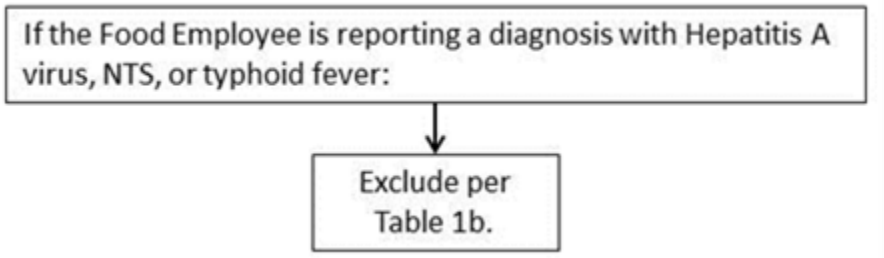
[2]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

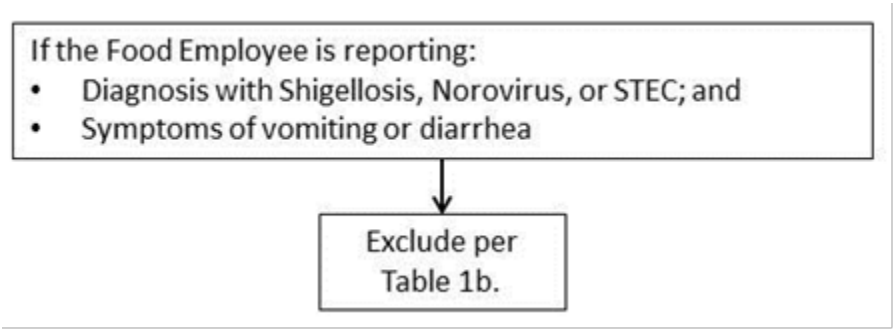
NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food employee and their manager.

There is no epidemiological evidence of an increased risk of NTS transmission from food employees in highly susceptible populations over the general population. Current evidence suggests that restriction is sufficient in food establishments that serve either highly susceptible populations or the non-highly susceptible populations to control transmission on NTS. Further, events where an infected food handler is involved in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011, only 41 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities and 16 outbreaks in hospitals, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, non-institutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code

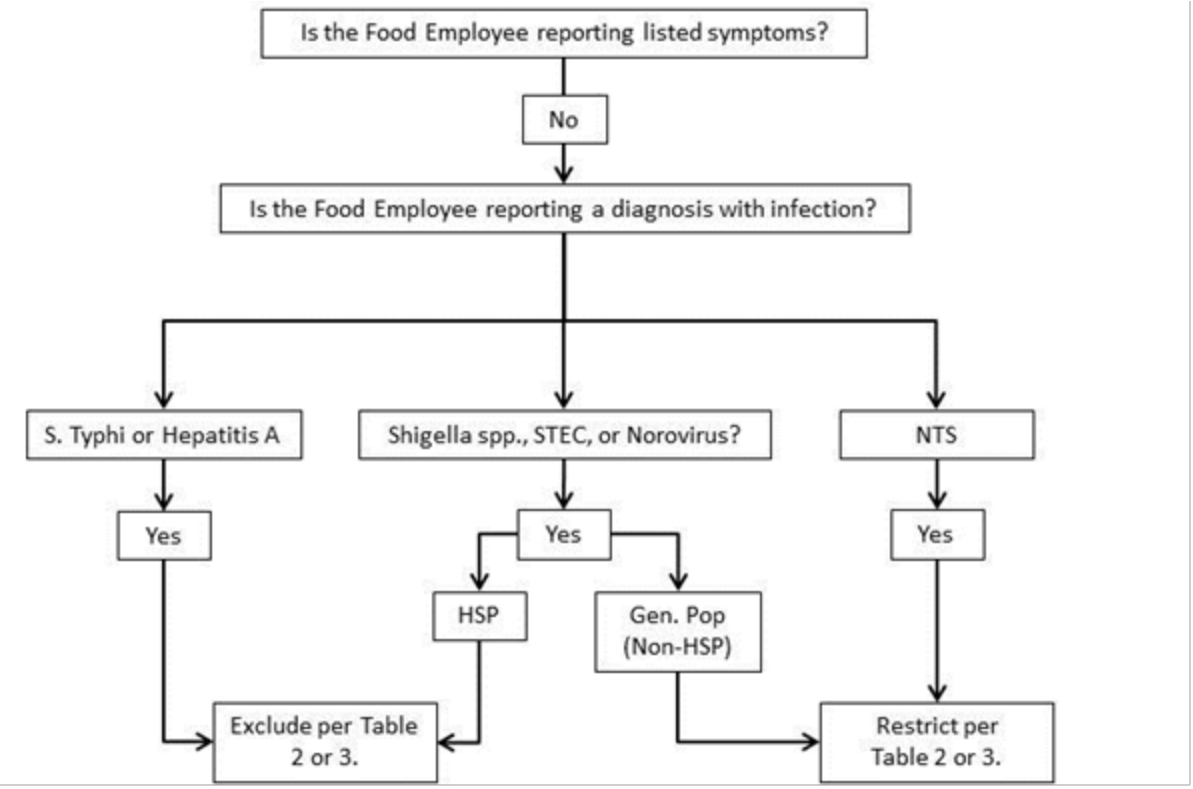






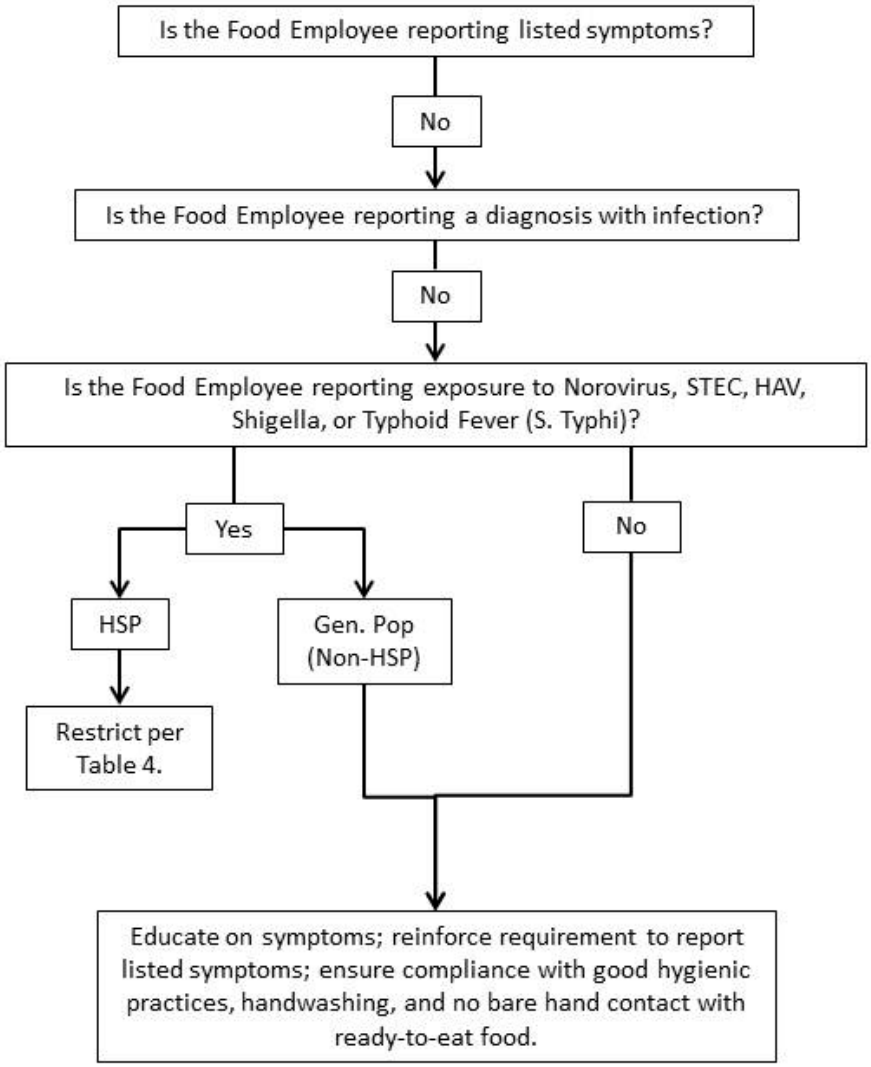
Key: Decision Tree 1
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2a. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis Under the Food Code



Key: Decision Tree 2a
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2b. When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key: Decision Tree 2b
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge

The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.

Symptom	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not serving an HSP)	Removing Symptomatic Food Employees from Exclusion or Restriction	RA Approval Needed to Return to Work?
Vomiting	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., STEC, HAV, or typhoid fever ***(S.* Typhi*)*** (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). ***Exceptions:*** If Diagnosed with Norovirus, STEC, HAV, or ***S.* Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13 (B), and: • Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • Food employee provides medical documentation 2-201.13(B)(3).	Yes
Sore Throat with Fever	**EXCLUDE** 2-201.12(G)(1)	**RESTRICT** 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	**RESTRICT** 2-201.12(I)	**RESTRICT** 2-201.12(I)	When the infected wound or boil is properly covered 2-201.13(I)(1)-(3).	No

Key: Table 1a
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed Diagnosis with symptoms immediately to the person in charge

- The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2).	Yes
Typhoid Fever (***S.* Typhi**)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2) (also see Table 2).	Yes
Nontyphoidal *Salmonella*	**EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)**	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)).	Yes **(continued)**

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
STEC	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility **(continued)**

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Shigella spp.	**EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)**	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(E), and • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

Key: Table 1b
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation that states the food employee is free of an ***S.* Typhi** infection 2-201.13)(C)(2) (also see Table 1b).	Yes
Nontyphoidal *Salmonella*	**RESTRICT** 2-201.12(G)	**RESTRIC**T 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)).	Yes **(continued)**

Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	1. <u>Serving a non-HSP facility</u>: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility</u>: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> • Approval is obtained from the RA 2-201.13(E), and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 201.13(E)(3)(a) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** **2-201.12(D)(1)**	**RESTRICT** **2-201.12(D)(2)**	1. <u>Serving a non-HSP facility</u>: 2-201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility</u>: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until</u>: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility **(continued)**

STEC	**EXCLUDE 2-201.12(F)(1)**	**RESTRICT 2-201.12(F)(2)**	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)**	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)**	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).	Yes

Key: Table 2
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid Fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a ***S*. Typhi** infection 2-201.13(C)(2).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Nontyphoidal *Salmonella*	**RESTRICT** 2-201.12(G)	**RESTRICT** 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee did not develop symptoms and >30 days have passed since the food employee was diagnosed (2-201.13(G)(3)).	**(continued)**

Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3).	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** 2-201.12(B)(3)	**EXCLUDE** 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3).	Yes

Key: Table 3
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge

- The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee
- The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Typhoid Fever (***S.* Typhi**)	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
STEC	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No **(continued)**

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Hepatitis A virus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When any of the following conditions is met: • The food employee is immune to HAV infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or • More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or • The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.	No

Key: Table 4
HSP = Highly Susceptible Population
BHC = Bare Hand Contact
RTE = Ready-To-Eat
GHP = Good Manufacturing Practices
STEC = Shiga toxin-producing *Escherichia coli*

2-201.12 Exclusion and Restrictions (continued)[3]

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 in outbreaks 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.

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 gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies to Norovirus, Hepatitis A, *Shigella* spp., STEC and *Salmonella* Typhi. It does not include nontyphoidal *Salmonella*.

Upon being notified of the history of exposure, the person in charge should immediately:

1. Discuss the traditional modes of transmission of fecal-oral route pathogens.

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 require immediate exclusion from the food establishment.

4. Remind food employees of their 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. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

---

[3]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

A restricted food employee may work in an area of the food establishment that houses packaged 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.

An excluded individual may not work as a food employee on the premises of any food establishment.

2-201.13 Removal of Exclusions and Restrictions.[4]

Food employees diagnosed with Norovirus, hepatitis A virus**, *Shigella*** spp., ***E. coli*** O157:H7 or other STEC, nontyphoidal *Salmonella* and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

---

[4]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC and initially symptomatic with vomiting or diarrhea, shall not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13 (F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(4).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus are excluded if they are within 14 days of any symptoms. Anicteric, diagnosed food employees shall be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a ***Salmonella*** **Typhi** infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (***Salmonella*** **Typhi**) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of ***S*****. Typhi** warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

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

The risk that food employees who are asymptomatic shedders will transmit a communicable disease 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. Exclusion in a food establishment that serves a highly susceptible population affords protection to people who are immune-suppressed. 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 provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

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 four 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 Manual."

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 RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission 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.

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

the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

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 and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they 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. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

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. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

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

2-301.13 Special Handwash Procedures.

This section is reserved.

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

2-301.14 When to Wash.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately before, during, or 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 sinks 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 Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log

reduction on the AOAC International's "Official Methods of Analysis 2003," which requires a minimum 5-log reduction in microorganisms to achieve "sanitization."

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for "sanitization." Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of "sanitization" in the Food Code.

The word "antiseptic" is a Greek term, meaning "against putrefaction", and eventually evolved into a second definition, meaning, "a substance used to destroy pathogenic microorganisms." The term "antiseptic" is often used to describe agents used on skin to prevent infection of the skin.

"Antiseptic" is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a "health-care antiseptic" as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An "antiseptic handwash" or "health-care personnel handwash drug product" is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin.

Replacing the term "hand sanitizer" with the term "hand antiseptic" allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

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

1. A hand antiseptic 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*. (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound and it is published annually with monthly supplements. However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand antiseptic 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 antiseptic 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 antiseptics 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, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This TFM, which was published in the ***Federal Register*** of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation & Research Food and Drug Administration 10903 New Hampshire Ave., Building 51, 5th Floor, Silver Spring, MD 20993. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

As a Food Additive

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

2. The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

   For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at (http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm). Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

3. The intended use of a substance may be the subject of a prior sanction, which is an explicit approval by the FDA or the United States Department of Agriculture (USDA) prior to September 6, 1958. All known prior sanctions are published under 21 CFR Part 181.

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Food Contact Substance (FCS) Notifications. This list is available on-line at: Inventory of Effective Food Contact Substance (FCS) Notifications (http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm). A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

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. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Food Code’s requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Food Code requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets are available through a number of different companies (*e.g.,* an internet search using the term “medical alert jewelry” leads to numerous suppliers).

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

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

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

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.

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

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

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

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

2-401.13 Use of Bandages, Finger Cots, or Finger Stalls.

Bandages, finger cots or finger stalls represent a potential physical hazard when worn by a food employee during food preparation. This hazard presents the risk of food products being directly contaminated by the introduction of a foreign object. The risk can be minimized through the use of a single-use glove to cover a bandage, finger cot or finger stall used on the wrist, hand or finger.

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.

2-501.11 Clean-up of Vomiting and Diarrheal Events.

When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident.

According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States. More specifically, Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis. Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. CDC estimates that 21 million cases of acute gastroenteritis are due to Norovirus infection.

Noroviruses can be highly contagious, and it is thought that an inoculum of as few as 10-18 viral particles may be sufficient to infect an individual. Transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.

In addition, the potential transmission level of Norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. One study found that employees who reported having cleaned up vomitus were more likely to contract illness that those who did not.

Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections. A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.

Consumers are at risk of contracting Norovirus illness from direct exposure to vomitus or from exposure to airborne Norovirus from vomitus. Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

The Food Code specifies that the Person in Charge is to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to Norovirus. A clean-up and response plan is intended to address situations where a food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative. Key to achieving an appropriate, timely response by food employees is the availability and access to a written plan upon which to refer to for reference.

When developing a written plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- the procedures for containment and removal of any discharges, including airborne particulates;
- the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;
- the procedures for the evaluation and disposal of any food that may have been exposed to discharges;
- the availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

When a food employee has been diagnosed, has recent history or exposure to, or is the suspect source of a confirmed disease outbreak of Norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11 (A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and ¶2-201.11(B). If a food employee has been diagnosed with Norovirus it must also be reported to the regulatory authority. Refer to public health reasons for §2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees for more information about appropriate employee health policies.

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 treatment 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.

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. Labeling should accompany the product to advise as to whether the product was frozen properly. 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 Fish

Except for raw molluscan shellfish, certain species of large tuna, certain aquacultured fish, and fish eggs that have been removed from the skein and rinsed, if fish are intended for raw or undercooked 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. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. 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 Juice

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.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) are not required to comply with this regulation.

Rather, the Food Code requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." 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.

Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; Final Guidance", October 7, 2002 which can be found at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm058962.htm or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

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. 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. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli O*157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy, and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word “irradiated,” or the labeling must bear a disclosure statement such as, “treated with radiation” or “treated by irradiation.” If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:

Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at http://www.fsis.usda.gov/wps/wcm/connect/058dd732-7fc8-4787-a283-30ed50d6f7e0/7700.1Rev1.pdf?MOD=AJPERES. Irradiation Questions & Answers can be found at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/irradiation-and-food-safety.

Labeling for Raw Shell Eggs

The Code of Federal Regulations 21 CFR 101.17 **Food Labeling warning, notice, and safe handling statements**, paragraph (h) *Shell* eggs state in subparagraph (1), "The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section."

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.

Refer also to public health reason for § 3-602.11.

3-201.12 Food in a Hermetically Sealed Container.

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

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

3-201.13 Fluid Milk and Milk Products.

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

3-201.14 Fish.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, 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.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: http://www.epa.gov/waterscience/fish/.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (http://www.epa.gov/waterscience/fishadvice/advice.html).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

States may issue safe-eating guidelines in addition to issuing fish advisories. A fish advisory is issued to warn the public of the potential human health risks from chemical contamination of certain species from particular types of waterbodies such as lakes, rivers, and/ or coastal waters within the State. In contrast, a safe-eating guideline is issued to inform the public that fish from specific waterbodies have been tested for chemical contaminants and the fish from these waters are safe to eat without consumption restrictions.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See August 2004 EPA Fact Sheet at http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

3-201.15 Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.
Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

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

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan

shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

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

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

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

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

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

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.
To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve

shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.

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

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that includes individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups.

Regulatory authorities have expressed their difficulty in regulating wild harvested mushrooms at retail. There are many different approaches in regulating the sale and service of wild harvested mushrooms. The differences in approach could be due to geography, the type of wild mushrooms that typically grow in a particular region and/or local/state laws that are enforced. The Conference for Food Protection (CFP) has attempted to develop a national model or standards for regulatory programs to address and recognize wild harvested mushroom identification. The difficulty in trying to get consensus on national model/standards lies in the question of what is the best national model/standard available that state/local regulatory authorities can apply in a meaningful way to ensure wild harvested mushrooms sold at retail are obtained from a safe source.

With the change in the codified text, the regulatory authority will have the flexibility to apply their laws and/or policies for wild harvested mushroom identification. At a minimum, when developing a wild harvest mushroom identification program, the following elements should be addressed:

- Developing resources & criteria to select wild mushroom species for service or sale,
- Establishing record-keeping and traceability to assure safety of wild harvested mushrooms,
- Written buyer specifications that include:
    a. Identification by the scientific name and the common name of the mushroom species,

b. A statement that the mushroom was identified while in the fresh states,
c. The name and contact information of the person who identified the mushroom and the mushroom seller, and
d. A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.

- Development of qualifications and training curriculum that could be used for further training of mushroom identifiers

In addition, the CFP has guidance material titled "Draft Model Guidance for Wild Harvested Mushrooms" posted on their website at http://www.foodprotect.org so state and local regulatory authorities can use the information to develop and implement their own wild harvested mushroom program. The guidance document is still a work in progress.

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 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF).

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

3-202.12 Additives.

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

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

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing&displayAll=false&page=17, and threshold of regulation exemptions are listed at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited from use in human food are listed in Title 21 CFR Part 189.

3-202.13 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.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in ***Salmonellae* 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 time/temperature control for safety 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.

When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under section 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

3-203.12 Shellstock, Maintaining Identification.

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

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

In reality and as stated in the provision, the 90-day “clock” starts at the time the container of shellstock is emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag discarded before an illness is reported and investigated.

Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days from the harvest date.

Freezing shellstock in the food establishment is not usually done because, although oysters-in-the-shell can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.

In November 1999, the National Advisory Committee on 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.

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. 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 employees and conditional employees 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 Norovirus or hepatitis A.

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

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.

If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary. Cooking foods to the temperatures required in the Food Code will reduce the likelihood of survival of pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods. The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in the Food Code. The exception does not apply when adding ready-to-eat foods as ingredients to foods that will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that are intended for preparation by the consumer offsite. When proper heat treatment is used in combination with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment provides an additional means of interrupting disease transmission.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

3-301.11(E) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

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.

Because highly susceptible populations include persons who are immunocompromised, the very young and the elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

(A) **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.

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

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

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions,** and

(2) **Exclusions and restrictions,** i.e., that food employees and conditional employees 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) **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 provisions described in paragraphs A-C 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 that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, 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.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions 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.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must 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.

Preventing Food and Ingredient Contamination

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

It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation, holding and display to prevent them from becoming contaminated by pathogens that may be present in or on the raw animal foods. An exception is permitting the storage and display of frozen, commercially packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

With regard to the storage of different types of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Separating different types of raw animal foods from one another during storage, preparation, holding and display will prevent cross-contamination from one to the other. The required separation is based on a succession of cooking temperatures as specified under § 3-401.11 which are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F (<1 second, instantaneous) due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

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 microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 Cleaning Procedure, before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. 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. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should <u>not</u> be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for

safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management 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 and was updated on August 19, 2003. This "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", October 26, 1998, is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued "Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A's for consumers on their website at: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

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 135ºF 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.

3-304.13 Linens and Napkins, Use Limitation.

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.

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 of adequate concentration between uses. 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.

Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces. However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop) the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food contact surface, when such is called for in 4-6 and 4-7 of the Food Code.

In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in Parts 4-6 and 4-7 of the Food Code, the surface must be first cleaned properly to remove organic material. In most cases this requires use of detergents or other cleaners such as described in Section 4-603.14 of the Food Code. After the surface is clean to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration should then be applied to the surface. The sanitizing solution must stay on the surface for a specific contact time as specified in this Code and in accordance with the manufacturer's EPA-registered label, as applicable.

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 Rubber Latex (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 NRL 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 Food Additive Safety, Division of Food Contact Notification, 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/docs/97-135/.

- 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://www.acaai.org/public/physicians/joint.htm.

  The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/allergic_conditions/latex_allergy.stm.

  The ACAAI provides information on latex allergies on the web at http://www.acaai.org/public/facts/latex.htm.

- 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.latexallergylinks.org/LA-TIB.html.

OSHA addresses gloves in the following Federal regulation, which can be found at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9788.

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.

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.

Food establishments may provide multi-use to-go containers to consumers with the intention that the containers are to be returned to the food establishment for refilling or reuse. These containers are likely to be soiled when the consumer returns the container to the food establishment. As a result, pathogens may be transferred to food by consumers or employees directly, or indirectly, from used take-home food containers. The existing provisions in the Food Code, specifically the cleaning and sanitization provisions in Parts 4-6 and 4-7, if carried out properly upon return of a used container, are sufficient to ensure that the container is safe to refill or reuse if performed in conjunction with a visual inspection by a food employee to verify that the container still meets the intent of the provisions in Parts 4-1 and 4-2. Reusing single-service and single-use articles is prohibited by the Food Code.

The refilling of consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, by a consumer or food employee 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, personal take-out beverage containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Preventing Contamination from the Premises

3-305.11 Food Storage.
3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety 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, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

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

3-306.12 Condiments, Protection.

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

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

3-306.13 Consumer Self-Service Operations.

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

Bean sprouts that are displayed in produce areas for consumer self-service are time/temperature control for safety 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 Re-Service 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 time/temperature control for safety foods 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). Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations listed in the chart in § 3-401.11 to meet a 6.5-$\log_{10}$ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.

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 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. Part 3-4 includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63ºC(145ºF), a time span of 15 seconds will provide a 3D reduction of ***Salmonella*** **Enteritidis** in eggs.

The requirements specified under ¶ 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under section 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.
Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even recooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus,*** are extremely heat stable and are not inactivated by normal recooking temperatures. Dwell times of greater than 6 hours in the 50°F to 130°F range should be viewed as especially hazardous, as the temperature range can foster substantial growth of many pathogens of concern.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in

which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Seared Steak

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

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

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

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

Pork

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

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68ºC (155ºF) for 17 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 68ºC (155ºF), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

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

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157ºF. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158ºF 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 158ºF 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 vegetative 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 <1 second (instantaneous) yield greater than a 7D reduction.

Children's Menu

The 2005 FDA Food Code Section 3-401.11 (D) "Raw Animal Foods" allows operators to serve raw or partially cooked animal food items on their customer's request, as long as the establishment does not serve a "Highly Susceptible Population" and the customer is informed of the risks associated with consuming undercooked items.

The definition of "Highly Susceptible Population" however, only includes young children who are of pre-school age and who obtain food under custodial care (as from a child daycare center). This definition does not address pre-school and older children eating in retail food establishments (such as restaurants), where it is common practice to offer menu items intended for children (e.g. "Kids Menu").

The Food Code seeks to increase current protection of children beyond custodial care facilities and establish needed safeguards in all retail food establishments. The importance of this issue can be demonstrated for numerous combinations of raw animal foods and associated pathogens. The greatest impact on children however, is undercooked ground beef, where the specific organism of concern is *Escherichia coli* O157:H7.

Children are at relatively high risk for infection with *E.coli* O157:H7. It is possibly the leading cause of acute kidney failure and Hemolytic Uremic Syndrome (HUS) in children [10]. Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: non-bloody or bloody diarrhea to HUS, which is a condition that includes destruction of red blood cells, problems with blood clotting and kidney failure. About 2% to 20% of patients that are infected with *E. coli* O157:H7 develop HUS [6]. The risk of illness from *E. coli* O157:H7 in ground beef has been shown to be about 2.5 times higher for preschool children and infants than for the rest of the population [6]. The CDC has reported the following *E. coli* 0157:H7 infection rates per 100,000 by age range: 8.2 for young children 1-9 years old and 3.0 for older children 10-20 years of age [4].

Precluding undercooked foods from being offered on a children's menu may result in increased protection to children from foodborne illness, particularly *E. coli* O157:H7, which can result in severe consequences in children.

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: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 57°C (135°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.

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Close attention must be paid to control of biological hazards when a food establishment cooks raw animal foods using a process in which the food is partially cooked then cooled with the expectation of fully cooking the food at a later date or time. Section 3-401.14 requires that establishments wishing to use a non-continuous process for the cooking of raw animal foods establish and follow a written plan that ensures each stage of the process is completed within time and temperature parameters that adequately prevent pathogen survival and growth. Section 3-401.14 also requires that establishments take special precautions to ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the consumer in a partially cooked state.

To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen growth, § 3-401.14 establishes limits on the time permitted to initially heat the food (initial "come-up" time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage. Together, these limits should prevent food from remaining at temperatures at which pathogen growth to harmful levels may occur.

The criteria in § 3-401.14 were developed with consideration of the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23 and 9 CFR 381.150. (http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr318.23.pdf, http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html)

The maximum one hour time limit for the initial heating stage was established based on estimates from predictive microbial modeling. It is intended to limit the cumulative growth of *Clostridium perfringens* that may occur during the come-up time and the subsequent cooling of the product in accordance with the requirements in ¶ 3-501.14(A). Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and times and then cooled may create an environment for the growth of ***Clostridium perfringens, Clostridium botulinum*** and other spore forming, toxigenic bacteria.

The product temperature achieved during the initial heating process may not be sufficient to destroy vegetative cells of ***Clostridium botulinum*****,** ***Clostridium perfringens*****,** and ***Bacillus cereus,*** if present***.*** The concern is the generation of a large number of vegetative cells of ***Clostridium perfringens*** and/or ***Clostridium botulinum*** before the final cooking stage. For ***Clostridium botulinum***, if enough vegetative cells are produced, toxigenesis can occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum required cooking temperatures. For ***Clostridium perfringens***, if a large number of vegetative cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come-up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

A full and adequate cook during the final cooking step is of critical importance to ensure destruction of any pathogens that may have survived and proliferated during any initial heating and cooling stages of the non-continuous cooking process. Section 3-401.14 requires that animal foods cooked by a non-continuous cooking process achieve a minimum final cook temperature that heats all parts of the food to a temperature and for a time specified under ¶¶3-401.11 (A)-(C). This requirement also precludes serving animal foods that have undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked using a non-continuous process are not covered in the exceptions provided for in ¶ 3-401.11(D) that allow for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

Section 3-401.14 requires that an establishment using non-continuous cooking processes also establish procedures for identifying foods that have only been partially cooked and cooled. This is necessary to ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore ready-to-eat without a full cook. Partially cooked foods may appear to be fully cooked.

Requiring that food establishments obtain prior approval by the regulatory authority before employing non-continuous cooking processes will help to ensure that the establishment has the proper procedures in place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking, separation and product identification of the foods. in accordance with the requirements.

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 Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw.

The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used.

Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance, Edition 4, Tables 3-2 and 3-3 (Chapter 3) lists those species for which FDA has information that a potential parasite hazard exists. Fish species in Tables 3-2 and 3-3 that do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked. This is because fish species in Tables 3-2 and 3-3 were not listed with a parasite hazard if the species were generally cooked before consumption. In addition, in some cases, there is insufficient information or data to be able to denote a specific parasite hazard or deem the species as naturally parasite-free. The exemptions to freezing as specified in ¶ 3-402.11(B) of the *Food Code* are inclusive of and in harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards and Controls Guidance.

Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures specified under ¶3-402.11(A) prior to sale or service in a raw or partially cooked form.

Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures specified under ¶3-402.11(A) prior to sale or service in a raw or partially cooked form.

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.

While the Country of Origin Labeling requirements, http://www.ams.usda.gov/COOL/ effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in the Fish and Fisheries Products Hazards and Controls Guidance, Table #3-1 – Potential Vertebrate Species Related Hazards and Table #3-2 – Potential Invertebrate Species Related Hazards.

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.

Shelf-stable, commercially prepared ready-to eat foods in hermetically sealed containers will have received a controlled retort process that destroys all bacterial pathogens, both vegetative cells and spores, to provide a commercially sterile product. Refrigerated, commercially processed, ready-to-eat, TCS food will have received controlled thermal processing that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration prevents spore germination. Because there is limited risk of contamination in these types of products, reheating such foods to the minimum hot holding temperature of 135°F is considered adequate when reheating for hot holding. This should be the case for product that remains in the container or package after it is opened, provided the proper steps are taken to protect the remaining portions from contamination and they are maintained at the appropriate cold holding temperatures as specified in the Food Code.

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

3-404.11 Treating Juice.

Refer to the public health reason for § 3-801.11.

Temperature and Time Control

3-501.11 Frozen Food.
3-501.12 Time/Temperature Control for Safety 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.

ROP Fish

Retailers should be aware that when a manufacturer packages fish and fishery products a hazard analysis is required under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule) to provide for control for nonproteolytic *C. botulinum.* Factors that make formation of *C. botulinum* toxin reasonably likely to occur during finished product storage and distribution are those that may result from the use of a reduced oxygen packaging (ROP) environment in a food that does not contain barriers to growth of *C.*

botulinum.

The processing control for *C. botulinum* can be either freezing, refrigeration alone or refrigeration in combination with chemical inhibitors, (e.g. salt, water activity control). The Fish and Fishery Products Hazards and Control Guidance, Fourth Edition, Chapter 13, addresses freezing as a control strategy for frozen product. This control is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in the closed ROP package.

If freezing was chosen by the manufacturer as the barrier to control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen and thawed according to the manufacturer's label instructions. Typically ROP fish will come into retail food establishments in a frozen state with a label that indicates to "thaw immediately before use" or indicates that the product needs to be "kept frozen, and thawed under refrigeration immediately before use."

If a "Keep Frozen" label is not present on each individual ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there are barriers such as pH or water activity to growth of *C botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have barriers to growth of *C. botulinum* in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41ºF or less for a prolonged time period and/or selling it as a refrigerated product.

3-501.14 Cooling.

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of time/temperature control for safety foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, time/temperature control for safety foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21ºC - 52ºC (70ºF - 125ºF), 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.

The Food Code provision for cooling provides for cooling from 135ºF to 41°F or 45°F in 6 hours, with cooling from 135ºF to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135ºF to 70ºF in 1 hour, in which case 5 hours remain for cooling from 70ºF to 41ºF or 45ºF. Conversely, if cooling from 135ºF to 41°F or 45°F is

achieved in 6 hours, but the initial cooling to 70ºF took 3 hours, the food safety hazards may not be adequately controlled.

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 time/temperature control for safety food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a time/temperature control for safety 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.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or

lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

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

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

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

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating

C. perfringens as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram.

In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens*** per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 ***C. perfringens*** per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index. Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization), is that product must be cooled from 130ºF to 80°F in 1.5 hours and from 80ºF to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

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

certain.

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

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 135ºF to 70°F in 2 hours and from 135ºF 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, time/temperature control for safety foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130ºF to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130ºF to 45°F in 15 hours permitted about 1 log growth of ***C. perfringens***.

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

1. The study did not address growth of ***C. botulinum****.*

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other time/temperature control for safety 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 Time/Temperature Control for Safety Food, Hot and Cold Holding.

Bacterial growth and/or toxin production can occur if time/temperature control for safety food remains in the temperature "Danger Zone" of 5°C to 57°C (41°F to 135°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

Maintaining TCS foods under the cold temperature control requirements prescribed in this code will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness. All microorganisms have a defined temperature range in which they grow, with a minimum, maximum, and optimum. An understanding of the interplay between time, temperature, and other intrinsic and extrinsic factors is crucial to selecting the proper storage conditions for a food product. Temperature has dramatic impact on both the generation time of an organism and its lag period.

When considering growth rate of microbial pathogens, time and temperature are integral and must be considered together. Increases in storage and/or display temperature will decrease the shelf life of refrigerated foods since the higher the temperature, the more permissive conditions are for growth.

The exception for holding time/temperature control for safety food in specially designed dispensing equipment recognizes technology designs that maintain the safety of aseptically-packaged fluid foods when the equipment is manufactured and operated in conformance with the NSF/ANSI Standard No. 18. NSF/ANSI 18 was revised in 2006, with FDA input, to address the storage of certain types of time/temperature for safety food or beverages in dispensing equipment without temperature control. The key condition for FDA allowing this exemption from 3-501.16 is that the equipment conforms to the requirements as specified in NSF/ANSI 18.

Except for raw shell eggs, control of the growth of ***Listeria monocytogenes*** (*Lm*) is the basis for the list of cold holding temperature and time combinations in paragraph 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food. The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Lm*, and do not set an acceptable number of *Lm* in food. Neither do they imply that *Lm* is in the product.

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

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

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

In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (risk assessment) at http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf.

This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

The risk assessment identified several broad factors that affect consumer exposure to *Lm* at the time of food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated storage before consumption, have a direct bearing on cold holding time/temperature combinations used in food establishments.

FDA continues to have concerns about the potential for growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food, prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment (see the following Annex 3, 3-501.16, Table 1) show a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41ºF. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of time/temperature control for safety foods, ready-to-eat foods to a maximum temperature of 41ºF.

3-501.16 – Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*

Maximum Refrigerator Temperature	Cases of Listeriosis[a] Median	Cases of Listeriosis[a] 5th Percentile	Cases of Listeriosis[a] 95th Percentile
Baseline[b]	2105	3/4[c]	3/4[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.
*The scenario assumed the distribution of storage times is the same for all three temperature sets.
Source: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998 Refrigeration and Labeling Requirements for Shell Eggs) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7ºC (45ºF). This regulation, however, does not apply to eggs while held at all retail establishments.

FDA is concerned that without continued refrigeration up until the time that the eggs are

cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella* Enteritidis** to occur. The agency reviewed research indicating that ***Salmonella Enteritidis*** multiplies at temperatures of 10ºC (50ºF) and above but can be inhibited at lower temperatures, e.g., 8ºC (46ºF), 7ºC (45ºF), and 4ºC (39ºF). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7ºC (45ºF) for eggs stored and displayed at retail establishments. Amended Federal regulations 21 CFR Part 115.50 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.

Historical Record of Cold Holding Temperature Provisions

The 1976 Food Service Sanitation Manual recommended 45°F as the cold holding temperature. Based on the available science at the time, the 1993 Food Code lowered the cold holding temperature to 41°F.

However, stakeholders raised concerns that many of the refrigerators currently in place in food establishments would not be capable of maintaining food at that temperature. There was also concern that most of the open-top buffet and food prep table-type units being built at the time could not reliably maintain food at 41°F or less. Industry pointed out that operators needed to recover investments in new refrigeration equipment purchased just before or after a state adopted the 41°F provision.

Consequently, the Conference of Food Protection (CFP) recommended the 1997 Food Code incorporate the option of having a 5-year phase-in period for the 41°F requirement to allow for upgrading of existing equipment, and the FDA agreed.

By 2006, many states adopted and implemented the phase-in period, the 5 years had expired and they were requiring cold holding at 41°F or less. In addition, NSF/ANSI Standard 7 was revised in 1997 and again in 1999 to ensure that equipment conforming to the Standard, including open-top and display units, could achieve the desired performance under conditions typically found in the food service and retail environments. Thus, there are mechanisms in place to allow industry flexibility in holding foods out of temperature control and the exemption for holding at 45°F was no longer necessary, given equipment capabilities, existing provisions of the Food Code that could be utilized (e.g., variances, time as a public health control), and the impact on

public health. Additionally, the FDA believed this exemption was no longer necessary and perhaps was detrimental to public health protection in light of what had been learned about the growth and survival of *Listeria monocytogenes* (LM) in refrigerated foods.

In 2006, the CFP recommended (CFP Issue 2006-I-033) and FDA agreed that the option of maintaining 45°F as a cold holding temperature be deleted from § 3-501.16. In the Supplement to the 2005 Food Code, the option to maintain 45°F as the cold holding temperature was deleted from the Food Code and 41°F became the standard for cold holding.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

3-501.17 Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.
3-501.18 Ready-to-Eat, Time/Temperature Control for Safety 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.

Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, time/temperature control for safety food may be kept at 5°C (41°F) a total of 7 days. 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. Time/temperature control for safety 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.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods at http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death

associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of ***L. monocytogenes*** in a ready-to-eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of ***Listeria monocytogenes***. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of ***Listeria monocytogenes***. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113942.htm), based on the presence of several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

List of Hard Cheeses Exempt from Date Marking	List of Semi-Soft Cheeses Exempt from Date Marking
Asadero	Asiago soft
Abertam	Battelmatt
Appenzeller	Bellelay (blue veined)
Asiago medium or old	Blue
Bra	Brick
Cheddar	Camosum
Christalinna	Chantelle
Colby	Edam
Cotija Anejo	Fontina
Cotija	Gorgonzola (blue veined)
Coon	Gouda
Derby	Havarti
Emmentaler	Konigskase
English Dairy	Limburger
Gex (blue veined)	Milano
Gloucester	Manchego
Gjetost	Monterey
Gruyere	Muenster
Herve	Oka
Lapland	Port du Salut
Lorraine	Provolone
Oaxaca	Queso de Bola
Parmesan	Queso de la Tierra
Pecorino	Robbiole
Queso Anejo	Roquefort (blue veined)
Queso Chihuahua	Samsoe
Queso de Prensa	Tilsiter
Romanello	Trappist
Romano	
Reggiano	
Sapsago	
Sassenage (blue veined)	
Stilton (blue veined)	
Swiss	
Tignard (blue veined)	
Vize	
Wensleydale (blue veined)	

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that ***Listeria monocytogenes*** does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of ***Listeria monocytogenes*** and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

Shellstock

Although ***Listeria monocytogenes*** has been isolated from shellstock there have been no reported Listeriosis cases linked to the consumption of this product at retail. The competitive microflora present in and on shellstock inhibits the growth of ***Listeria monocytogenes*** to harmful levels when the product is held under refrigeration at retail. Therefore shelllstock are exempt from date marking.

USDA-regulated products

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

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

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

The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (non-time/temperature control for safety food) 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 as a Public Health Control.

The 2000 Conference for Food Protection (CFP) meeting 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 the 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 time/temperature control for safety food 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 or for up to 6 hours for refrigerated food, if the food is 5°C (41°F) when initially removed from temperature control, and as long as the food temperature does not exceed 21°C (70°F). 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 time/temperature control for safety foods RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that time/temperature control for safety foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

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.

---------- End of position paper ---------

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of ***Listeria monocytogenes,*** and the influence of time and temperature on its growth.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for ***Listeria monocytogenes*** in ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows time/temperature control for safety food to be stored up to 6 hours without external temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or above) to Ambient

FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4 hours without temperature control starting with an initial temperature of 135°F or above. *Clostridium perfringens* was chosen to represent a worst case scenario pathogen for foods allowed to cool from cooking temperatures to ambient without temperature control, because its spores can survive normal cooking procedures, it can grow at relatively high temperatures (>120°F) and it has a short lag period. *C. perfringens* spores were inoculated into foods that were cooked and then cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional 2-hour margin of safety built-in for consumer handling.

Consumer Handling Practices

An Audits International study was funded in 1999 by FDA to determine the food handling practices of consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are represented, and the data comprises several food groups purchased from different grocery-store types. The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat, pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen novelties and whipped topping.

The study evaluated information regarding time and food temperature at retail food stores, time to reach home refrigeration, temperature after transport home, location and type of retail establishment where purchase was made and type of product purchased.

For product temperature at retail and after transportation, 5 product categories were used: pre packaged lunch meat, pre packaged deli product, deli counter products, seafood and fresh meat. These categories were considered most applicable to the TPHC recommendations. The temperature ranges for these products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data suggest that with current retail refrigeration practices, 25% of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98% of products were at 65°F or less (Figure 2).

The time of transport for all food categories from the retail establishment to home refrigeration was also recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for frozen entrées were included. Because all foods end up bagged and transported together, the time each product was transported to the home was considered a valid data point and therefore used. Based on the data, a benchmark was established that TCS foods purchased in a food establishment would be either consumed, or placed under temperature control, within 2 hours.

Figure 1. Temperatures of refrigerated products at retail (Audits International).

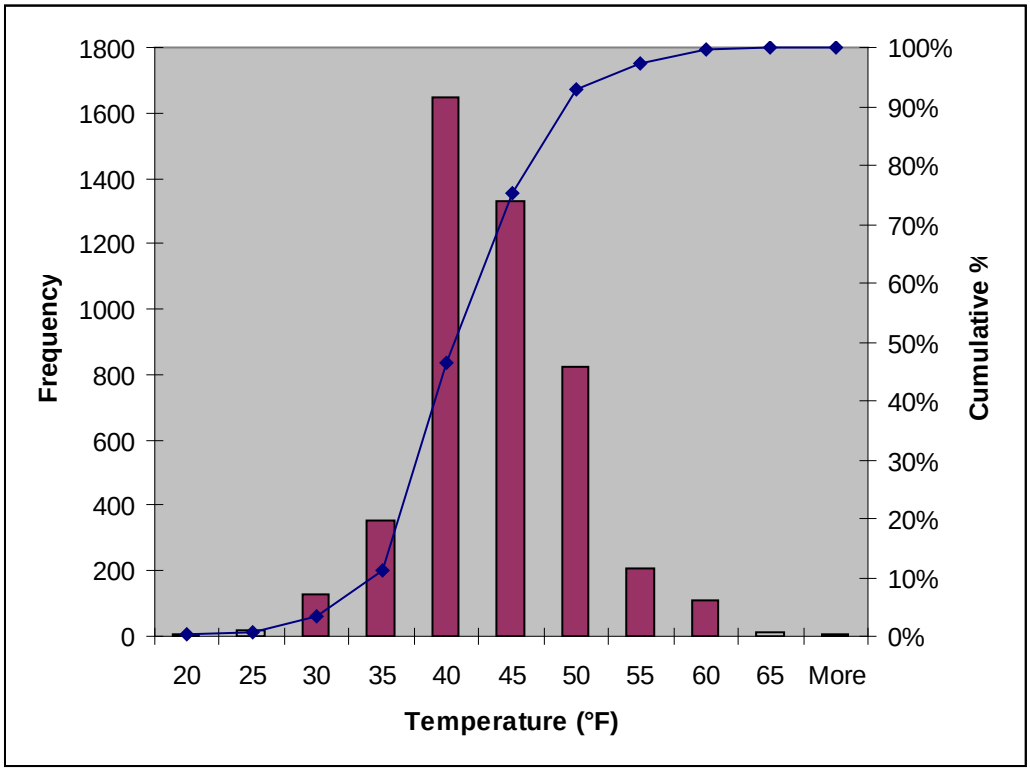


Figure 2. Product temperatures after transport to the home (Audits International).

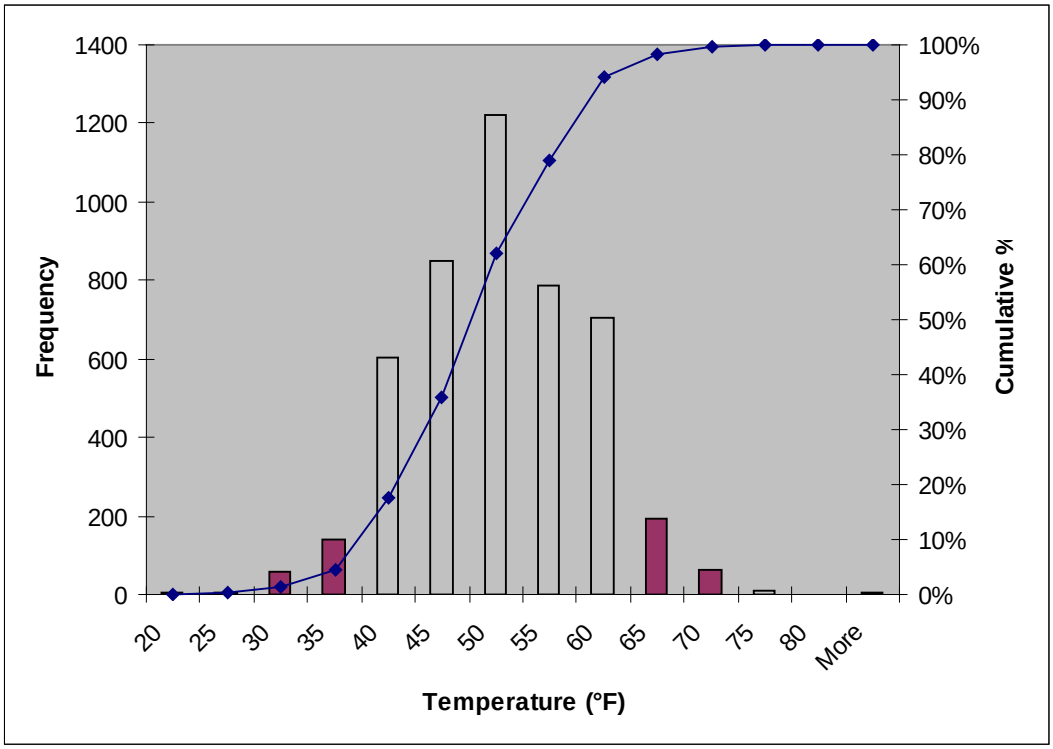
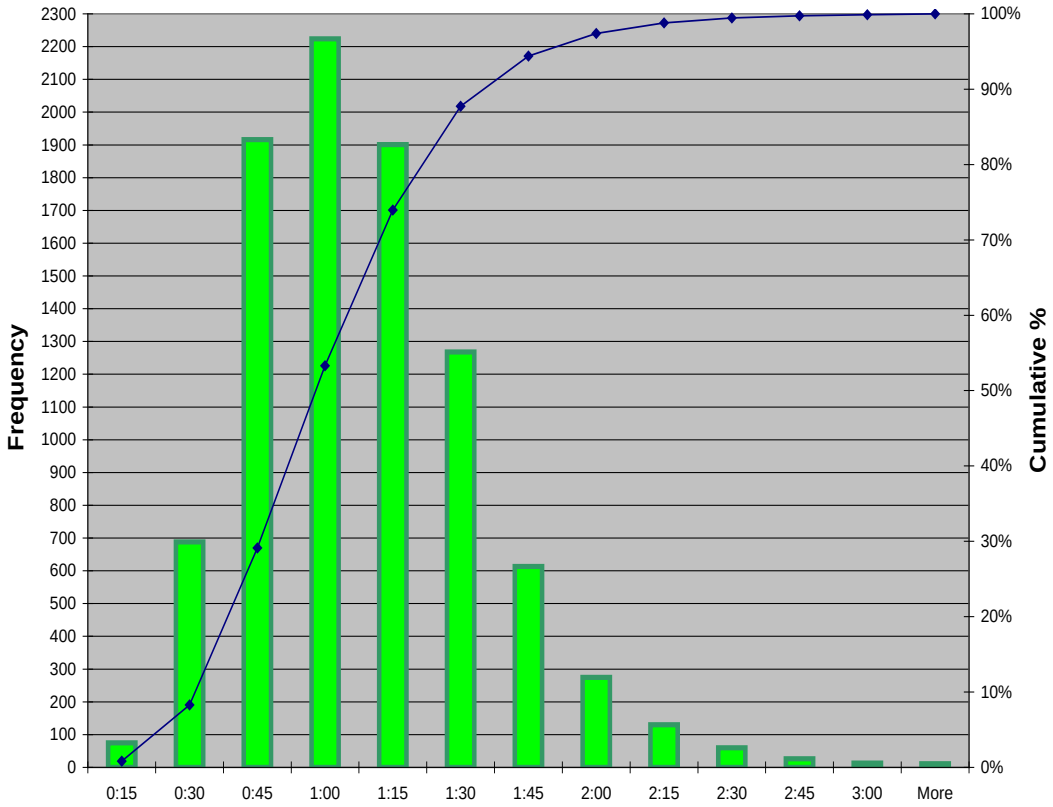


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).



The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (41°F or less) to Ambient

As noted above, the current TPHC provision has two time provisions. Food can be kept with no temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and served, served if RTE, or discarded within the four hours. However, if food does not exceed 70°F, it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to determine the safety of the existing TPHC recommendations.

Assuming pathogen growth in foods going from refrigeration (41°F or less) to ambient temperature, the following parameters were used for the PMP simulation:

- 65°F was used as the temperature for the entire simulation;
- 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);
- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

Table 1 summarizes the predicted growth of *Bacillus cereus* (vegetative), *Escherichia coli*, *Listeria monocytogenes*, Salmonella spp., *Shigella flexneri*, and *Staphylococcus aureus*, using the PMP and based on the assumptions discussed above. The data predicted that less than 1-log growth would be seen for each organism, during the 8 hour time period. Thus, the data show that the current 4 and 6 hour TPHC provisions from 41°F or less to ambient, allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.

Pathogens	6 Hours	8 hours
B. cereus (vegetative cells)	0.62	0.87
E. coli	0.35	0.52
L. monocytogenes	0.47	0.71
Salmonella Spp.	0.25	0.41
S. flexneri	0.26*	0.34*
S. aureus	0.38*	0.51*

* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

References

U.S. Department of Agriculture. 1997. *Pathogen Modeling Program.* USDA Agricultural Research Service, Wyndmoor, PA.

Food and Drug Administration. 2006. Growth of *Clostridium perfringens* inoculated into beef roasts and meatloaf (unpublished data).

---------- End of Summary of Consumer Handling Practices study **----------**

Raw eggs

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

Specialized Processing Methods

3-502.11 Variance Requirement.

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

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

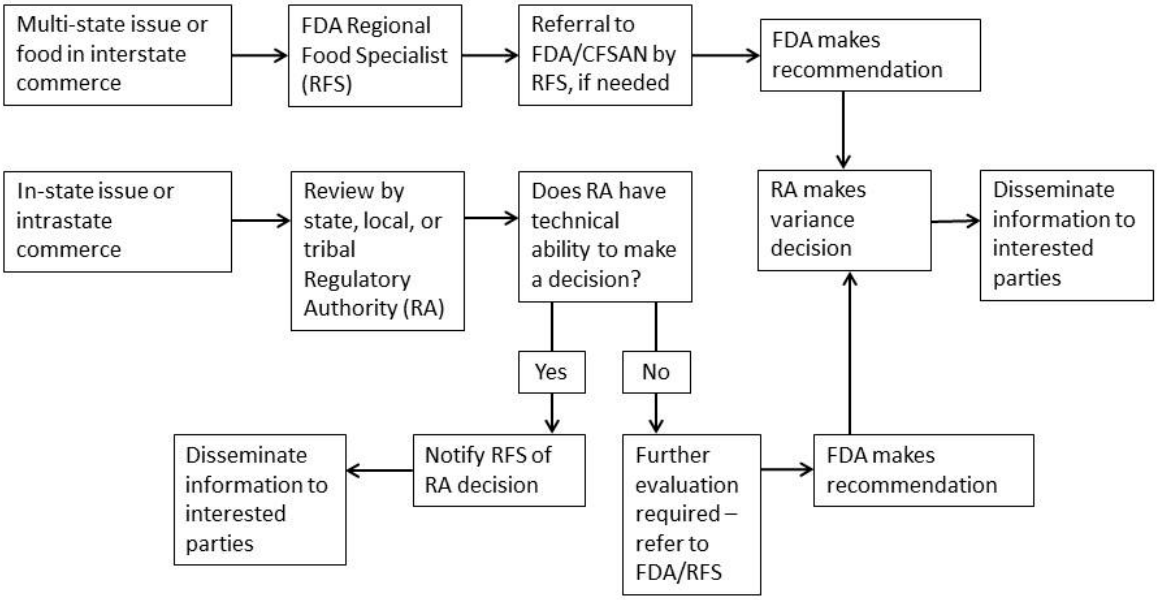
Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

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

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

3-502.11 Chart 1 – 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 Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits related to time and labor savings, portion control and quality retention. However, ROP can also increase the potential for the growth of certain pathogens in the absence of the growth of competing spoilage organisms. For example, if certain controls are not in place, the formation of ***C. botulinum*** toxin may occur before spoilage renders the product unacceptable to the consumer.

The type of food, the production and packaging methods used, and the packaging material can impact the level of oxygen present within a package and within the food matrix. Combinations of some or all of these variables may result in an oxygen level within a package, or within a food matrix, that is less than 21%. While ROP may involve different foods and different packaging materials, each process is characterized by the deliberate removal of oxygen from or the reduction in the oxygen level in the package or the food matrix at the time of packaging.

Certain foodborne pathogens that are anaerobes or facultative anaerobes are able to multiply under either aerobic or anaerobic conditions. Therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to multiply well below 5°C (41°F). For this reason, ***C. botulinum*** and ***L. monocytogenes*** are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

Reduced Oxygen Packaging with Two Barriers

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes*** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. These barriers are:

- a_w of 0.91 or less;
- pH of 4.6 or less;
- cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or

- high levels of competing microorganisms such as those found on raw meat or raw poultry or raw vegetables.

The barriers described above are effective controls for **C. *botulinum*** and **L. *monocytogenes*** in reduced oxygen packaged foods because**:**

- ***C. botulinum*** will not produce toxin below an a_w of 0.91*,* and the minimum a_w for growth of ***L. monocytogenes*** is 0.92.
- ***C. botulinum*** will not produce toxin when the pH is 4.6 or below and ***L. monocytogenes*** will generally not grow at this pH under refrigeration temperatures.
- Nitrite, used in meat and poultry curing, inhibits the outgrowth of ***C. botulinum*** spores.
- Most foodborne pathogens do not compete well with other microorganisms. Therefore foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 5°C (41°F).

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes****.*

Foods that are not time/temperature control for safety food (TCS) should not support the growth of ***C. botulinum*** and ***L. monocytogenes.*** Therefore the reduced oxygen packaging HACCP requirements of sections 3-502.11 or 3-502.12, apply only to TCS foods.

Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of ***C. botulinum*** and ***L. monocytogenes,*** such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses. When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes****.* Non-proteolytic ***C. botulinum*** spores are able to germinate and produce toxin at temperatures down to 3ºC (38ºF). Therefore, holding ROP foods at 3ºC (38ºF) or less should prevent the formation of ***C. botulinum*** toxin. ***L. monocytogenes*** is able to grow, although very slowly, at temperatures down to - 1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Three separate options are provided in (D)(2)(e).

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (***L. monocytogenes*** will be eliminated by the cooking procedures specified in ¶¶3-401.11(A), (B) and (C) and recontamination will be prevented by filling the product into the bag while it is still hot (cook-chill) or by cooking in the sealed bag (sous vide). ***C. botulinum*** will not grow under the specified time-temperature combinations.)

Since there may not be other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaged product, continuous monitoring of temperature control and visual examination to verify refrigeration temperatures is important. New technology makes it possible to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures that can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook-chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Reduced Oxygen Packaging with Cheese

Cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following:

- a lower pH;
- salt (NaCl) added during processing;
- low moisture content;
- added preservatives; and
- live competing cultures.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on the intrinsic factors in these cheeses plus the refrigeration temperature of 41°F or less to maintain safety. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic ***C. botulinum*** (primarily type E) which grows at 3ºC (37-38ºF). ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard.

HACCP Plans with Reduced Oxygen Packaging

A Hazard Analysis and Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most TCS foods. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used. Developing a HACCP plan and providing a copy to the regulatory authority prior to implementation provides notice to the regulatory authority that the food establishment intends to conduct ROP operations and makes it possible to verify that the appropriate ROP procedures are being followed and that the requirements of §3-502.12 are being met.

When a food establishment intends to conduct ROP and hold the product for more than 48 hours without using one of the secondary barriers defined in section 3-502.12 (the criteria specified in paragraph 3-502.12(D) combined with holding the product at 5°C (41°F) or less, or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), it is important that an application for a variance (under section 3-502.11) provide evidence that the ROP methodology intended for use is safe.

The Relationship Between Time and Reduced Oxygen Packaging

Time is also a factor that must be considered in ROP at retail. The use of date labels on VP, MAP, and CAP products and assuring those dates do not exceed the manufacturer's "sell by" or "use by" date is intended to limit the shelf life to a safe time period (based on a time in which growth will not occur or involves the presence of two barriers to growth). When these ROP products are frozen, there is no longer a restricted shelf life. The shelf life limits for cook-chill and sous-vide foods are based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 1°C (34°F) or less for 30 days or 5°C (41°F) or less for 7 days after packaging, with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook-chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook-chill and sous-vide processes.

3-502.12 (F) exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements in section 3-502.12 because growth and toxin formation by anaerobic pathogens in that limited time frame is not considered a significant hazard in such foods.

Accurate Representation

	3-601.11	**Standards of Identity.**
	3-601.12	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness outbreak 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.

Food Labels and other forms of Information

Food labels serve as a primary means by which consumers can make informed decisions about their food selections. Many items in a food establishment are provided by the food employee to the consumer upon consumer request. When a consumer orders a specific food or specific amount of food from a food employee, that employee may put the food in a wrapper or carry-out container at the time the order is placed. This food is not considered “packaged”, per the Food Code definition; it was merely wrapped or placed in a carry-out container to facilitate service and delivery of the food to the consumer in a protected manner. When food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about ingredients, nutrients, allergens and weight.

Alternatively, some food items are enclosed in a container or wrapping for use in the display of that item for consumer self-service. In these instances, the label provides an important source of information for consumers to answer questions about ingredients, allergens, weight, and manufacturer.

List of Ingredients

A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food. In some instances, an ingredient itself may be composed of two or more ingredients, or sub-ingredients. In accordance with 21 CFR 101.4(b)(2), the sub-ingredients must be declared on the label. One example includes parenthetically listing the individual sub-ingredients in descending order of predominance after the common or usual name of the main ingredient, as illustrated here:

- Bread pudding ingredients: bread (*wheat flour, water, yeast, salt, honey*), milk, eggs, and sugar

Another example is to incorporate the common or usual name of each sub ingredient into the list of ingredients in descending order of predominance in the finished food without listing the main ingredient itself, as illustrated here :

- Bread pudding ingredients: milk, wheat flour, water, eggs, sugar, yeast, salt, and honey.

Food Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) require that all affected packages of food labeled on or after January 1, 2006 identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. Providing the name of the food source on the label of packaged foods alerts consumers to the presence of a major food allergen and may prevent an inadvertent exposure. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Nutrition Labeling

The requirements for nutrition labeling are found in the CFR. 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)(6) if they do not bear a nutrient content 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 packaged food products if:

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

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

(C) Except as provided in 21 CFR 101.11, 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) Except as provided in 21 CFR 101.11, 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) Except as provided in 21 CFR 101.11, 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.

Canthaxanthin and Astaxanthin

Canthaxanthin and Astaxanthin are color additives 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. These color additives may be in the feed that is fed to aquacultured fish. When those fish are placed into a bulk container for shipment, the

bulk container will bear a label declaring the presence of canthaxanthin.
Providing this information on the label of fish packaged and offered for sale at retail will inform the consumer of the presence of these additives

21 CFR 73.75 promulgates requirements for the use of canthaxanthin in salmonid fish.
21 CFR 73.35 promulgates requirements for the use of astaxanthin in salmonid fish.
For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification, Canthaxanthin.

Safe Handling Instructions

Refer to public health reason for § 3-201.11 Labeling for Meat and Poultry.

Consumer Advisory

3-603.11 Consumption of Raw or Undercooked Animal Foods.

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

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as "hidden ingredients, " for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in § 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. A third option for the consumer "reminder" was added later. 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. Essential criteria for such written information are available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740. All brochures must meet these essential criteria. 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.

The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code* (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740.

Locating the Advisory:

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

Educational Messages:

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

Applicability:

Food Establishments:

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

"*... Otherwise Processed to Eliminate Pathogens... ":*

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

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

Recognition of Other Processes:

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

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving 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 "meat" rather than "beef, lamb, and pork" and "seafood" rather than "fish" are used. Categorical terms like "meat" are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007973.htm. 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 Consumer Advisory Reminder, paragraph 3-603.11(C), 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 Re-Service, 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 a "juice" means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. 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. Further information is available at the FDA website, http://www.fda.gov, by entering “sprouts” in the search window.

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 operating 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(F)(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**.

3-801.11(G) and (H) Re-service of food

The Food Code addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is not permitted. The "isolation or quarantine" terminology in the Code text refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a "protective environment" isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

Multiuse **4-101.11 Characteristics.**

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

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

4-101.13 Lead, Use Limitation.

Historically, lead has been used in the formulation 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.

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).

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.

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. Metals such as iron and steel are coated with zinc to prevent rusting. Under certain conditions, zinc may leach from galvanized food-contact surfaces into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized food-contact surface. On contact with acidic foods and beverages, the zinc may be converted to zinc salts which are readily absorbed by the body

Zinc is generally considered to be non-toxic, and in fact is a required mineral for many processes that occur in the human body. However, zinc is known to be toxic when ingested in large quantities. Symptoms of zinc poisoning include vomiting, nausea, lethargy, fatigue, and epigastric pain. Most reports of zinc poisoning implicate contaminated food that resulted from storage in a galvanized metal container.

Also see http://www.cdc.gov/mmwr/preview/mmwrhtml/00000082.htm

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 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.

4-101.18 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.

4-101.19 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, 1996, and 2004, 15 USC 205a et seq) 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, 1996, and 2004, 15 USC 205a et seq) 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.

NSF/ANSI 18-*Manual Food and Beverage Dispensing Equipment* is the standard for manual food and beverage dispensing equipment which has been designed to maintain the safety of aseptically packaged fluid foods without refrigeration even after the hermetic seal is broken.

NSF/ANSI 18 was revised in 2006 to specifically address dispensing equipment designed to hold time/temperature control for safety food or beverages in a homogeneous liquid form without temperature control. NSF/ANSI 18 requires that such equipment designs include a number of safeguards that prevent the contamination of specially packaged food stored within the dispensing equipment. The Standard also requires that the dispensing equipment have lockout mechanisms that preclude the dispensing of the product if such safeguards fail or if a prescribed duration of storage is exceeded.
The American National Standards Institute (ANSI) recognizes NSF/ANSI 18 as the sole American National Standard for the sanitary design of manual food and beverage dispensers.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.

Failure to store time/temperature control for safety food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all time/temperature control for safety 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 time/temperature control for safety 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 time/temperature control for safety 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.

4-204.121 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, Movability.

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 time/temperature control for safety 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 time/temperature control for safety 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 (0.059 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.

Effective mechanical hot water sanitization occurs when the surface temperatures of utensils passing through the warewashing machine meet or exceed the required 71°C(160°F). Parameters such as water temperature, rinse pressure, and time determine whether the appropriate surface temperature is achieved. Although the Food Code requires integral temperature measuring devices and a pressure gauge for hot water mechanical warewashers, the measurements displayed by these devices may not always be sufficient to determine that the surface temperatures of utensils are reaching 71°C(160°F). The regular use of irreversible registering temperature indicators provides a simple method to verify that the hot water mechanical sanitizing operation is effective in achieving a utensil surface temperature of 71ºC (160ºF).

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.

4-303.11 Cleaning Agents and Sanitizers, Availability

If the appropriate cleaning agents and sanitizers are not on hand at all times they may not be available when needed to clean and sanitize equipment and utensils. It is also important that the cleaning agents and sanitizers be on hand, even at times where warewashing may not be in progress, so that their suitability can be verified by the regulatory authority and, if needed, by personnel who are responsible for servicing the equipment.

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 time/temperature control for safety 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. Contact time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

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

4-501.13 Microwave Ovens.

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

4-501.14 Warewashing Equipment, Cleaning Frequency.

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

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

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

4-501.16 Warewashing Sinks, Use Limitation.

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

4-501.17 Warewashing Equipment, Cleaning Agents.

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

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

4-501.18 Warewashing Equipment, Clean Solutions.

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

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110ºF, 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 77ºC (171ºF), 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 hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer’s specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71ºC (160ºF) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90ºC (194ºF) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74ºC (165ºF) for a stationary rack, single temperature machine, and 82ºC (180ºF) for other machines are based on the sanitizing rinse contact time required to achieve the 71ºC (160ºF) utensil surface temperature.

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.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quat) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

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

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on

the EPA-registered label, section 7-204.11 would be violated.

To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong 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.

A variety of hard food contact surface sanitizers such as sodium hypochlorite or hypochlorous acid, can be generated on-site by technologies known as electrolyzed water, electro chemically activated water, and electro activated water in pesticide generating devices. Paragraph 4-501.114(F) addresses the efficacy and use of these on-site generated solutions and Section 4-703.11 requires that the conditions of use yields sanitization as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

Because EPA does not require registration of solutions generated and used on-site, the user of the equipment should look to the device manufacturer for data to validate the efficacy of the solution produced by the device as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site in the food establishment.

Any data used to validate efficacy of on-site generated sanitizer solutions should include validation testing that includes all factors that could impact the efficacy of the sanitizer solution, including water hardness, pH, temperature, and a time element because efficacy can reduce with time. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. See the EPA web site at http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html. According to the web site, “EPA’s Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under FIFRA section 5 of the Toxic Substances Control Act (TSCA), and pursuant to testing consent agreements and test rules issued under section 4 of TSCA.”

Verifying the adequacy of chlorine-based solutions can be accomplished on an on-going basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using acceptable test methods and equipment.

The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment consistently generates a solution on-site at the necessary concentration to achieve sanitization.

Devices can be used for years to produce chemicals intended for the washing of fruits and vegetables, (e.g., hypochlorous acid, ozone, and chlorine dioxide). Other devices that are capable of producing hard food contact surface cleaning and sanitizing

solutions on-site (e.g., chlorine, hypochlorous acid that are generated by processes known as electrolyzed water, electro chemically activated water, and electro activated water).

A device used to generate hard food contact surface sanitizers on-site is considered a pesticide device. The Environmental Protection Agency (EPA) defines a device in 40 CFR 152.500, Requirements for devices, as "(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom."

The EPA does not require the registration of pesticide devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as 40 CFR 152.500 Requirements for Devices and 156.10 Labeling Requirements. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this regulation include, but are not limited to:

- The name, brand, or trademark under which the product is sold ·
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Maintaining and cleaning devices used for the on-site generation of sanitizing solutions in accordance with manufacturer's specifications will help to ensure that they continue to generate the sanitizer chemicals in the form and concentration for which their efficacy was assessed.

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.

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments. This prohibition does not apply to the removal of the oyster or other species from the shell for preparation, then returning the same animal to the same shell for service.

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

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

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

Frequency **4-602.11 Equipment Food-Contact Surfaces and Utensils.**

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for time/temperature control for safety 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^{o}F or less and 55^{o}F.

Surfaces of utensils and equipment contacting food that is not time/temperature control for safety food 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, Other Consumer Protection Activities). 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.

The 2012 Conference for Food Protection (CFP) requested that FDA amend §4-602.11 of the Food Code to require that equipment food contact surfaces and utensils that have contacted raw animal foods that are major food allergens be cleaned before use with other raw animal foods (Issue 2012-III-024). FDA recognizes that in addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. While most cross-contact can be avoided through control of the environment during food production and preparation, the CFP request only addresses allergen cross-contact from raw animal foods that are major food allergens and therefore, falls short of comprehensive allergen cross-contact control for all eight (8) major food allergens. Although limited in scope, such a change supports the continued efforts of FDA to work in cooperation with the Conference for Food Protection toward control of food allergens in retail food establishments. Therefore, §4-602.11 was amended to require that food contact surfaces of equipment and utensils that have contacted raw animal foods that are major food allergens, such as raw fish, must be cleaned and sanitized prior to contacting other types of raw animal foods.

Refer also to Annex 4 - Management of Food Safety Principles for Food Allergens as Food Safety Hazards.

4-602.12 Cooking and Baking Equipment.

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

4-602.13 Nonfood-Contact Surfaces.

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

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not time/temperature control for safety foods. 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 fixed or too large 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.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

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

Frequency **4-702.11 Before Use After Cleaning.**

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

Methods **4-703.11 Hot Water and Chemical.**

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

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71ºC (160ºF), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

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.

Preventing Contamination

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

The presentation 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.

4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.

The rinsing of cleaned and sanitized utensils and equipment in a manner that may contaminate the surfaces before they are used, such as running them under a faucet or by dipping them in a vessel of water, is prohibited. The application of a post-sanitizing rinse is restricted to warewashing machines because there will be little opportunity for contamination of the potable water rinse if applied within the confines of a compliant warewashing machine. Provided the sanitization is achieved before the rinse is applied and as long as any chemical sanitizers are used in accordance with an EPA-registered label, the sanitary state of utensils and equipment should not be altered by applying a potable water rinse after the required final sanitizing rinse within a warewashing machine.

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 and 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 by nondrinking water. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

Irrigation water used in the cultivation of fresh produce, e.g. herb gardens or other onsite gardens, is another example of nondrinking water. Whenever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination. Water has the potential to be a direct source of contamination and vehicle for spreading contamination. Research has shown that irrigation water can increase the frequency of pathogen contamination of harvested produce, and may contain or convey pathogens, such as *Salmonella* spp. Where used, irrigation water should be adequate and approved for its intended use in accordance with Good Agricultural Practices (GAPs) that minimize the potential for contaminated water to contact the edible portion of the crop. FDA's "*Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruit and Vegetables*" provides useful information about GAPs and safely growing, harvesting, washing, sorting, packing and distributing produce. It is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm.

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 Sink, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of 40°C ± 2°C (100 to 108°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 Sinks.

Because handwashing is such an important intervention in the control of foodborne illness, sufficient handwashing sinks must be available to make handwashing not only possible, but likely to occur at all appropriate times and places as outlined in Sections 2-301.14 and 2-301.15.

According to Greig et el. (July 2007) an analysis of 816 reported outbreaks of infected worker-associated outbreaks from 1927-2006 found that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them are attributed to schools, day care centers and health care institutions. The two most frequently reported risk factors associated with these implicated food workers was bare hand contact with food, and failure to properly wash hands.

Green et al (JFP, March 2007) found that handwashing was more likely to occur in restaurants whose food workers received food safety training, had more than one handwashing sink, and had a handwashing sink in the observed worker's sight. This suggests that improving food worker hand hygiene requires more than food safety education.

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.

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 Sinks.

Hands are a common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. The transfer of contaminants can be limited by providing food employees with handwashing sinks that are properly equipped and conveniently located.

A handwashing sink that is properly located is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Handwashing sinks that are blocked by portable equipment or stacked full of soiled utensils and other items, are rendered unavailable for employee use. Nothing must block the approach to a handwashing sink thereby discouraging its use, plus it must be kept clean and well stocked with soap and sanitary towels to facilitate frequent use. Therefore, a handwashing sink that is located in the immediate work area, or between work areas that the Code states must be equipped with handwashing sinks, depending upon the size and function of the facility, would be considered properly located. Such placement of handwashing sinks facilitates frequent handwashing by food employees in all work areas.

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 Sink.

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.

The exception in paragraph 5-402.11(B) allows for a direct connection to the sanitary sewer system for floor drains originating in refrigerated spaces that are constructed as an integral part of the building structure. Examples of refrigerated spaces that are considered an integral part of the building include refrigerated prep rooms, meat cutting rooms, and refrigerated storage rooms. The exception specifically targets refrigerated spaces that are considered an integral part of the building. It does not apply to prefabricated walk-in refrigerators and freezers with prefabricated floors. It is not intended to apply to pieces of equipment, including those which may be located in a refrigerated room and which indirectly drain to a floor drain within the room. Drainage from equipment is addressed under paragraph 5-402.11(A).

5-402.12 Grease Trap.

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

5-402.13 Conveying Sewage.
5-402.14 Removing Mobile Food Establishment Waste.

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

5-402.15 Flushing a Waste Retention Tank.

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

Disposal Facility

5-403.11 Approved Sewage Disposal System.

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

5-403.12 Other Liquid Waste and Rainwater.

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

Facilities on the Premises

5-501.10 Indoor Storage Area.
5-501.11 Outdoor Storage Surface.
5-501.12 Outdoor Enclosure.
5-501.13 Receptacles.
5-501.14 Receptacles in Vending Machines.
5-501.15 Outside Receptacles.
5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.
5-501.17 Toilet Room Receptacle, Covered.
5-501.18 Cleaning Implements and Supplies.
5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.
5-501.110 Storage Refuse, Recyclables, and Returnables.
5-501.111 Areas, Enclosures, and Receptacles, Good Repair.
5-501.112 Outside Storage Prohibitions.
5-501.113 Covering Receptacles.
5-501.114 Using Drain Plugs.
5-501.115 Maintaining Refuse Areas and Enclosures.
5-501.116 Cleaning Receptacles.

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions,

makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal **5-502.11 Frequency.**
5-502.12 Receptacles or Vehicles.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling

5-503.11 Community or Individual Facility.

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

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 Code, 2009 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 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 Sinks

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.

It is known that wet hands transfer bacteria more readily than dry hands. The residual moisture found on the hands after washing allows for bacterial and viral transfer to food or solid surfaces by touch. The method in which hands are dried is a critical factor in reducing chances of cross-contamination by hands to food and environmental surfaces (Patrick et al., (1997)).

With regard to the addition of air knife technology for hand drying, data reviewed by FDA scientists at the FDA's National Center for Food Safety Technology (Moffitt Center) demonstrates that the use of this technology in hand dryers has been found to be equivalent to the hand drying treatment in existing heated-air devices.

While the Food Code does not specifically address the configuration or ergonomic design of hand drying devices, technologies employing air knife systems do not appear to accommodate the drying of one's arms and may not be large enough to accommodate surrogate prosthetic devices for hands and arms to fit within the hand-dryer. In the case where food employees are expected to wash their forearms or are fitted with a surrogate prosthetic device, the food establishment would need to provide an alternate means for drying of the arms and certain prosthetic devices.

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 sinks 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 Sinks

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 Cleaning of Plumbing Fixtures.

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.

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.

Hand contact with contaminated surfaces can result in self-inoculation by touching of the nose and mouth. The spread of *Shigella sonnei* in a nursery school has been traced to contaminated toilets. Experiments by Gerba, et al and Barker and Bloomfield have shown that when bacteria and viruses were seeded into a household toilet, the detection of bacteria and viruses in the fallout droplets from the aerosols produced when flushing remain airborne long enough to settle on surfaces throughout the bathroom. Barker and Bloomfield also demonstrated that *Salmonella* Enteritidis could be isolated from the air surrounding a household toilet after flushing the toilet.

Noroviruses which are a major cause of gastroenteritis can be transmitted by fecal-oral, airborne inhalation, person-to-person and environmental-to-person routes. Norovirus, which is highly infectious, is shed in vomitus and stool in high numbers. A study was conducted by J. Barker et al to look at the transmission of norovirus via fingers, cloths and contact surfaces. The results indicated that where fingers come into contact with virus-contaminated toilet tissue, norovirus is consistently transferred via the fingers to a melamine surface and from there to other typical hand-contact surfaces such as taps, door handles and telephone receivers. In this study epidemiological evidence suggests that environmental spread from an infective person occurs by settling of aerosol particles on to contact surfaces. Hands can then spread the virus when they touch toilet seats or flush handles contaminated by splash from vomit or aerosol particles generated during toilet flushing.

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 humans by contaminating food and food-contact surfaces. Effective measures must be taken to eliminate their presence in food establishments.

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

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

6-501.113 Storing Maintenance Tools.

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

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

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

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

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

6-501.115 Prohibiting Animals.

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

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

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

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

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the Federal agency which has the lead in these matters, in documents such as, “Commonly Asked Questions About Service Animals in Places of Business”; “The Americans with Disabilities Act Questions and Answers”; “A

Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://adata.org/.

Chapter 7 Poisonous or Toxic Materials

Original Containers

7-101.11 Identifying Information, Prominence.

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers

7-102.11 Common Name.

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11 Separation.**

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

Presence and Use

7-202.11 Restriction.

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

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the

manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.

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

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

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

Container Prohibitions

7-203.11 Poisonous or Toxic Material Containers.

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

Chemicals **7-204.11 Sanitizers, Criteria.**

See explanation in §4-501.114.

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

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940, Tolerance

exemptions for active and inert ingredients for use in antimicrobial formulations (food contact sanitizing solutions) or 40 CFR 180.2020, Non-food determinations. Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution.

Some sanitizers produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. Occupational Safety and Health Administration (OSHA) limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000, Air contaminants. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

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 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 approved food additives or food-contact substances, generally recognized as safe, prior sanctioned or exempted by the threshold of regulation process can be used. Information regarding food contact substances notification may be found on the FDA website under the Food Topic in Ingredients and Packaging section at: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm

Chemicals that are not generally recognized as safe, or not authorized by FDA for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), or a request for exemption under the Threshold of Regulation. Wash chemicals, boiler water additives, 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. If the chemicals are hard food-contact sanitizers, or washes for raw agricultural commodities (RACs) that are used on a farm or in a packing house, then this is under the jurisdiction of the EPA.

21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption includes a number of regulations permitting certain food additives to be used for washing fruits and vegetables. In an effort to be consistent with federal law a change was made in Section 7-204.12 Chemicals for Washing, Treatment, Storage and

Processing Fruits and Vegetables, Criteria to include all of 21 CFR 173 so as not to exclude the use of other permitted food additives. There is also another mechanism for approval of antimicrobial agents for washing fruits and vegetables (i.e., the food contact notification program) as well as GRAS ingredients permitted as antimicrobials or for general food use. This revision allows for the use of ingredients that are GRAS for this use and food contact substances which were the subject of an effective food contact notification for this use. 21 CFR 173 includes permitted food additives such as those listed in 21 CFR 173.315 Chemicals used in the washing or to assist in the peeling of fruits and vegetables. This section specifically identifies some of the chemicals that may be used in washing fruits and vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding the minimum amount required to accomplish the intended technical effect. FDA has no objection to the use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

On December 4, 2012, the FDA amended the food additive regulations to provide for the safe use of sodium dodecylbenzenesulfonate (SDBS) (CAS No. 25155-30-0) as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. 21 CFR Section 173.405 specifically identifies this additive as an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse. Use of this additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments and other food service operations in which food is prepared for or served directly to the consumer. To ensure safe use of the additive, refer to the label or labeling of the additive and/or antimicrobial pesticide container for adequate directions. Information on the label is required in accordance to provisions within 21 CFR 173.405 and the Federal Food, Drug and Cosmetic Act. Although the petitioned use of SDBS is regulated under Section 409 of the FD & C Act as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA requirements pertain to EPA registered pesticide products that have uses subject to EPA or both FDA and EPA regulations. Therefore, manufacturers intending to use this food additive for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Lubricants **7-205.11 Incidental Food Contact, Criteria.**

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.11 Restricted Use Pesticides, Criteria.**
7-206.12 Rodent Bait Stations.

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.

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

Medicines **7-207.11 Restriction and Storage.**

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

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

7-207.12 Refrigerated Medicines, Storage.

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

First Aid Supplies

7-208.11 Storage.

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

Other 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

Construction Inspection and Approval

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 FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm.

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 operating

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) Time/temperature control for safety 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 paragraph 2-103.11(N) 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.

8-304.11 Responsibility of the Permit Holder

It is important that regulatory agencies comply with applicable laws related to disclosure of public information. Making inspection reports available to the public promotes transparency and allows the public to be better informed about the businesses they patronize and the government agencies that serve the public. The intent is to improve

industry and regulatory practices related to food safety at the foodservice and retail level.

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *FDA's Recommended National Retail Food Regulatory Program Standards* (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm) to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

8-403.50 Public Information.

Regulatory documents that describe the compliance status of a regulated food establishment may be of particular interest to consumers, academia, industry, and other regulators. Certain laws may obligate government entities to make regulatory documents available to the public upon request. Proactively making these documents available to the public, by way of a website, may reduce the burden associated with requesting these documents, and therefore make it more likely that these documents will be accessible and reviewed by interested stakeholders.

8-404.11 Ceasing Operations and Reporting.

During crisis, industry and public health are partners with a common purpose; to restore normalcy to the community quickly while protecting the public health in the process. Pre-approval of emergency operating plans by the regulatory authority enables food establishments to remain in operation under conditions of loss of electrical service or water service and allows the regulatory authority to ensure in advance that appropriate precautions are planned for and taken to provide food safety protections under pre-determined and agreed upon parameters.

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

See discussion in Annex 3, § 2-201.12.