

**IMPORTANT - Save this Supplement.** It is intended to keep the 2001 Food Code up to date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2001 Food Code effective upon issuance.

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## **Introduction**

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2001 Food Code (hereafter referred to as Supplement). This Supplement updates the 2001 Food Code to address several recommendations made by the 2002 Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect the current

science and emerging food safety issues, and imminent health hazards related to food safety.

From 1993 through 2001, the complete Food Code has been issued every two years. With the support of the Conference for Food Protection, FDA has decided to move to a four-year interval between complete Food Code revisions. The next complete revision of the Food Code will be published in 2005. Until that time, this Supplement allows several changes upon which there is substantial concurrence among the Federal Agencies and the other stakeholders to be incorporated into the Food Code. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2005. This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.

While the recommendations of the 2002 Conference for Food Protection meeting provide the basis for the Food Code changes contained in this Supplement, not all recommendations of the 2002 CFP meeting were incorporated. Some recommendations require further consideration or research by one or more of the Federal agencies. FDA anticipates that most of the 2002 CFP recommendations with which the Federal agencies agree will be addressed in the 2005 Food Code.

The Supplement has been organized to facilitate the adoption of its provisions by Federal, state, local, and tribal authorities. The Supplement is divided into 3 Parts:

- Part 1 - Summary of Changes - a "quick view" of the modifications
- Part 2 - Amendments, Additions, Deletions to Chapters 1-8 and the Annexes - actual language modifications
- Part 3 - New Terms for the Index to the Food Code

For consistency, drafting conventions used in the *Federal Register* for proposed rules are used in the Supplement to the 2001 Food Code. The standard terms to be used to describe a change are:

**Amend.** "Amend" means that an existing Food Code provision has changed. Because it is an introductory term, it is always used with one of the following specific amendatory terms to precisely describe the change to the Food Code provision.

#### Amendatory Terms

**Add** - means a new provision has been inserted in the Food Code.

**Redesignate** - means to modify a Food Code provision by reformatting the text of the provision into a new structural nomenclature designation.

**Remove** - means an existing provision is being taken out of the Food Code.

**Revise** - means an existing Food Code provision is replaced in part, or in its entirety.

For example:

**Amend** § 4-204.110 to **revise** subparagraph (B)(1) and to **add** subparagraph (B)(3) to read as follows: [text of changed subparagraph and newly added subparagraph]

Modifications are organized by Food Code chapter and are identified by Section number and title, and the paragraph, (e.g., 9-101.11(A)) or subparagraph (e.g., 9-101.00(A)(1)) to which the change is made. The full text of a Section is provided only if necessary to provide the proper context. Using Chapter 3 as an example, a change is introduced as follows:

## **Chapter 3 Food**

*Amend § 3-202.11 to revise paragraph (D) to read as follows:*

### ***Specifications for Receiving***

#### **3-202.11 Temperature.\***

[text of changed paragraph]

Using Chapter 4 as an example, a change to the Annexes is introduced as follows:

## **Annex 3 Public Health Reasons/Administrative Guidelines**

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

*Amend Public Health Reason for § 4-501.112 to revise to read as follows:*

[text of changed paragraph]

We encourage all jurisdictions to examine the level of food safety protection their current rules and implementation strategies provide and take the steps necessary to increase that level in light of the 2001 Food Code and its Supplement. Food Code adoption and implementation in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system.

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

**IMPORTANT.** This entire Supplement to the 2001 Food Code is intended to keep the 2001 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2001 Food Code effective upon issuance.

## **Part 1 Summary of Changes**

The amendments to the 2001 Food Code and its Annexes contained in the Supplement are summarized below. If an amendment relates directly to a recommendation of the Conference for Food Protection (CFP), the CFP issue number is provided in parenthesis immediately after the summary entry.

### **Preface**

#### **Item 9(A)**

Revised the Food Code revision cycle from 2 years to 4 years (CFP Issue 2002-II-22)

#### **Item 10**

Revised the Acknowledgements paragraph to update the text

### **Chapter 1 Definitions**

Added definitions for the terms "disclosure" and "reminder" (CFP Issue 2002-II-20)

### **Chapter 2**

#### **2-102.11(A)**

Added language to define what is meant by "complying with this Code" with respect to demonstration of knowledge by the person in charge (CFP Issue 2002-I-28)

#### **2-301.16(A)(2)**

Revised the criteria for hand sanitizers to more accurately and concisely identify current federal food additive regulations that relate to hand sanitizer formulations and redesignated (A)(2) as (A)(2)(a)-(d)

### **Chapter 3**

**3-202.11(D)**

Revised hot holding temperature requirement for receiving potentially hazardous foods from 60°C (140°F) to 57°C (135°F). (CFP Issue 2002-III-14)

**3-301.11(B) and (C)**

Revised language of paragraph (B), redesignated paragraph (C) as paragraph (D) and added new paragraph (C) prohibiting bare hand contact with ready-to-eat food by food employees in food establishments serving highly susceptible populations (CFP Issue 2002-III-24)

**3-304.12(F)**

Revised hot holding temperature requirement for storing in-use utensils from 60°C (140°F) to 57°C (135°F). (CFP Issue 2002-III-14)

**3-304.14**

Added new paragraph (E) to address storage of wiping cloth containers (CFP Issue 2002-I-31)

**3-306.13(A)**

Revised and redesignated paragraph (A) as subparagraphs (A)(1) and (A)(2) regarding consumer self-service operations (CFP Issue 2002-I-04)

**3-401.11(D)**

Added language regarding a consumer's selection of raw or under cooked animal foods (CFP Issue 2002-II-21) and a reference to 3-801.11 (C) (1)-(2)

**3-401.13**

Revised hot holding temperature requirement for plant food cooking and hot holding, from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

**3-403.11(C)**

Revised hot holding temperature requirement involving reheating for hot holding from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

**3-501.14(A)**

Revised the initial timed cooling temperature from 60°C (140°F) to 57°C (135°F) and clarified the intent of the cooling parameters (CFP Issue 2002-III-40)

**3-501.16 (A)(1)**

Revised hot holding temperature requirement for potentially hazardous foods from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

**3-502.12(B)(5)**

Revised to include "except the time the product is maintained frozen" (CFP Issue 2002-III-38)

### **3-603.11**

Revised to require a disclosure and reminder for satisfactory compliance with the consumer advisory provision (CFP Issue 2002-II-20)

### **3-801.11**

Revised the section title by removing the words, "Prohibited Reservice"

Removed prohibition of the re-service of food in an unopened, original package to highly susceptible populations (CFP Issue 2002-I-01)

Added prohibition of bare hand contact with ready-to-eat food for food employees in food establishments serving highly susceptible populations (CFP Issue 2002-III-24)

## **Chapter 4**

### **4-204.111(B)(2)**

Revised vending machine automatic shutoff requirement for potentially hazardous foods that are held hot from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

### **4-204.117**

Removed the words, "designed and" from the introductory phrase to clarify that the warewashing machine's features prescribed in this section are not necessarily integrated into the machine design by the manufacturer and instead may be added at the time of installation

### **4-602.11(D)(7)**

Revised hot holding requirement for in-use utensils stored in water from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

## **Chapter 8**

### **8-402**

Revised Subpart title to include "competency" (CFP Issue 2002-II-14)

### **8-402.10**

Added new paragraph to address competency of inspectors (CFP Issue 2002-II-14)

## **Annex 2**

### **3-501.16**

## **2. BIBLIOGRAPHY**

Added new references for the hot holding of potentially hazardous food

## **Annex 3**

**2-301.16**

Expanded the explanation of the applicable federal regulations pertaining to substances that are "generally recognized as safe (GRAS)" and substances that are the subject of a Food Contact Substance Notification in relation to their use in hand sanitizers

**3-301.11**

Added explanation for prohibiting bare hand contact in establishments serving highly susceptible populations

**3-401.11**

Added new paragraph to the introductory text regarding a consumer's right to select raw or undercooked animal foods

**3-501.14**

Revised to include additional information on cooling

**3-501.16**

Amended the temperature "Danger Zone," by replacing 60°C (140°F) with 57°C (135°F) and added discussion of the temperature criteria for hot holding of potentially hazardous foods

**3-502.12**

Added new paragraph discussing the use of proper cooling and freezing in reduced oxygen packaged products

**3-603.11**

Added new paragraphs under, "Satisfactory Compliance" that provides additional information on how to achieve compliance with the disclosure and reminder requirements for consumer advisories

**4-501.112**

Revised the section to specify the temperature parameters of a warewasher using hot water for sanitizing

**4-703.11**

Revised the section to discuss the utensil surface temperature that must be reached to ensure sanitization

**8-402.10**

Added new section to address the competency of inspectors

**Annex 4****3. STAFF TRAINING**

**Revised the introductory text**

## **Part 2 Amendments, Additions, Deletions to Chapters 1-8 and the Annexes**

### **Preface**

#### **9. THE CODE REVISION PROCESS**

*Amend § 9 to revise paragraph (A) to read as follows:*

FDA is issuing a new edition of the Food Code every 4 years. During the 4-year span of time between editions, FDA may issue supplements to an existing edition. Each new edition will incorporate the changes made in the supplement as well as any new revisions.

#### **10. ACKNOWLEDGMENTS**

*Amend § 10 to revise the paragraph to read as follows:*

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

## **Chapter 1 Purpose and Definitions Amendments, Additions, and Deletions**

*Amend § 1-201.10 to add to paragraph (B) the following defined terms:*

### ***Applicability and Terms Defined***

#### **1-201.10 Statement of Application and Listing of Terms.**

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

(B) Terms Defined.

**Disclosure.**

"**Disclosure**" means a written statement that clearly identifies the animal-derived foods which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

**Reminder.**

"**Reminder**" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

**Chapter 2 Management and Personnel  
Amendments, Additions, and Deletions**

*Amend § 2-102.11 to revise paragraph (A) to read as follows::*

**2-102.11 Demonstration.\***

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

- (A) Complying with this Code by having no violations during the current inspection;
- (B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM; or
- (C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:
  - (1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;
  - (2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;
  - (3) Describing the symptoms associated with the diseases that are transmissible through FOOD;
  - (4) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD and the prevention of foodborne illness;

- (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH;
- (6) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD including MEAT, POULTRY, EGGS, and FISH;
- (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD;
- (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
  - (a) Cross contamination,
  - (b) Hand contact with READY-TO-EAT FOODS,
  - (c) Handwashing, and
  - (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair;
- (9) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:
  - (a) Sufficient in number and capacity, and
  - (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;
- (10) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;
- (11) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
- (12) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW;
- (13) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;
- (14) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the establishment; and
- (15) Explaining the responsibilities, rights, and authorities assigned by this Code to the:
  - (a) FOOD EMPLOYEE,
  - (b) PERSON IN CHARGE, and
  - (c) REGULATORY AUTHORITY.

***Amend § 2-301.16 to revise subparagraph (A)(2) and redesignate as (A)(2)(a)-(d) to read as follows:***

## 2-301.16 Hand Sanitizers.

- (A) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:
  - (1) Comply with one of the following:
    - (a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness; or
    - (b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, and
  - (2) Consist of components that are:
    - (a) Listed for such use in contact with FOOD in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*; or
    - (b) Exempt from regulation as FOOD ADDITIVES under 21 CFR 170.39 - *Threshold of regulation for substances used in food-contact articles*; or
    - (c) Generally recognized as safe (GRAS) for the intended use in contact with FOOD within the meaning of the Federal Food, Drug and Cosmetic Act (FFDCA); or
    - (d) Permitted for such use by an effective Food Contact Substance Notification as defined by paragraph 409(h) of the FFDCA and listed in FDA's Inventory of Effective Premarket Notifications for Food Contact Substances; and
  - (3) Be applied only to hands that are cleaned as specified under § 2-301.12.

## Chapter 3 Food Amendments, Additions, and Deletions

*Amend § 3-202.11 to revise paragraph (D) to read as follows:*

### *Specifications for Receiving*

#### **3-202.11 Temperature.\***

- (A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD shall be at a temperature of 5°C (41°F) or below when received.
- (B) *If a temperature other than 5°C (41°F) for a POTENTIALLY HAZARDOUS FOOD is specified in LAW governing its distribution, such as LAWS governing*

*milk and MOLLUSCAN SHELLFISH, the FOOD may be received at the specified temperature.*

- (C) Raw shell EGGS shall be received in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.
- (D) POTENTIALLY HAZARDOUS FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 57°C (135°F) or above.
- (E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.
- (F) Upon receipt, POTENTIALLY HAZARDOUS FOOD shall be free of evidence of previous temperature abuse.

***Amend § 3-301.11 to revise paragraph (B), redesignate paragraph (C) as paragraph (D), and add a new paragraph (C) to read as follows:***

## ***Preventing Contamination by Employees***

### ***3-301.11 Preventing Contamination from Hands\****

- (A) Food EMPLOYEES shall wash their hands as specified under § 2-301.12.
- (B) *Except when washing fruits and vegetables as specified under § 3-302.15 or as specified in ¶ (C) of this section,* FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.
- (C) *When otherwise APPROVED,* FOOD EMPLOYEES *not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hands.*
- (D) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.<sup>S</sup>

***Amend § 3-304.12 to revise paragraph (F) to read as follows:***

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

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

- (A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;
- (B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;
- (C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD

preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

- (D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;
- (E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or
- (F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

***Amend § 3-304.14 to add new paragraph (E) to read as follows:***

### **3-304.14 Wiping Cloths, Use Limitation.**

- (E) *Working containers of sanitizing solutions for storage of in-use wiping cloths may be placed above the floor and used in a manner to prevent contamination of food, equipment, utensils, linens, single-service or single-use articles.*

***Amend § 3-306.13 to revise and redesignate paragraph (A) as paragraph (A) and subparagraphs (A)(1) and (A)(2) to read as follows:***

### **3-306.13 Consumer Self-Service Operations.\***

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

***Amend § 3-401.11 to revise paragraph (D) to read as follows:***

## ***Cooking***

### **3-401.11 Raw Animal Foods.\***

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

*served or offered for sale upon consumer request or selection in a READY-TO-EAT form if:*

- (1) *As specified under 3-801.11(C)(1)-(2), the FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION, and*
- (2) *The consumer is informed as specified under § 3-603.11 that to ensure its safety, the FOOD should be cooked as specified under ¶ (A) or (B) of this section; or*
- (3) *The regulatory authority grants a VARIANCE from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP PLAN that:*
  - (a) *Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,*
  - (b) *Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe FOOD, and*
  - (c) *Verifies that EQUIPMENT and procedures for FOOD preparation and training of FOOD EMPLOYEES at the FOOD ESTABLISHMENT meet the conditions of the VARIANCE.*

***Amend § 3-401.13 to revise to read as follows:***

### **3-401.13 Plant Food Cooking for Hot Holding.**

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F).

***Amend § 3-403.11 to revise paragraph (C) to read as follows:***

### **3-403.11 Reheating for Hold Holding.\***

- (A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.
- (B) Except as specified under ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
- (C) READY-TO-EAT FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD PROCESSING PLANT that is inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding.

- (D) Reheating for hot holding shall be done rapidly and the time the FOOD is between the temperature specified under ¶ 3-501.16(B) and 74°C (165°F) may not exceed 2 hours.
- (E) *Remaining unsliced portions of roasts of beef that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

***Amend § 3-501.14 to revise paragraph (A) to read as follows:***

### **3-501.14 Cooling.\***

- (A) Cooked POTENTIALLY HAZARDOUS FOOD shall be cooled:
  - (1) Within 2 hours, from 57°C (135°F) to 21° C (70°F); and
  - (2) Within a total of 6 hours, from 57°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).
- (B) POTENTIALLY HAZARDOUS FOOD shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.
- (C) Except as specified in ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).
- (D) Raw shell EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

***Amend § 3-501.16 to revise subparagraph (A)(1) to read as follows:***

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

- (A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-501.19, and except as specified in ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD shall be maintained:*
  - (1) At 57°C (135°F) or above, *except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above;* or
  - (2) At a temperature specified in the following:
    - (a) 5°C (41°F) or less; or
    - (b) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:

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

*Amend § 3-502.12(B) to revise subparagraph (B)(5) to read as follows:*

## ***Clostridium botulinum Controls***

### **3-502.12 Reduced Oxygen Packaging, Criteria.\***

- (B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and *Clostridium botulinum* is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:
  - (5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

**Amend § 3-603.11 to revise to read as follows:**

## ***Consumer Advisory***

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

- (A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased risk of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in paragraphs (B) and (C) of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.
- (B) DISCLOSURE shall include:
  - (1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order);" or

- (2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.
- (C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:
  - (1) Regarding the safety of these items, written information is available upon request;
  - (2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or
  - (3) Consuming raw or undercooked MEATS , POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions."

*Amend § 3-801.11 to remove the words, "Prohibited Reservice" from the tag line to revise the title to read as follows:*

### *Additional Safeguards*

#### **3-801.11 Pasteurized Foods and Prohibited Food.\***

**Amend § 3-801.11 to remove paragraph (C), redesignate paragraph (D) as paragraph (C), and add new paragraph (D) to read as follows:**

### *Additional Safeguards*

#### **3-801.11 Pasteurized Foods and Prohibited Food.\***

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

- (A) The following criteria apply to JUICE:
  - (1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;
  - (2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, Section 101.17(g) *Food Labeling*, or a PACKAGED JUICE OR BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; and
  - (3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 - *Hazard Analysis and Critical Control Point (HACCP) Systems*, Subpart B *Pathogen Reduction*, 120.24 *Process controls*.

- (B) Pasteurized shell EGGS or pasteurized liquid, frozen, or dry EGGS or EGG products shall be substituted for raw shell EGGS in the preparation of:
  - (1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and EGG-fortified BEVERAGES; and
  - (2) Except as specified in ¶ (E) of this section, recipes in which more than one EGG is broken and the EGGS are combined.
- (C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:
  - (1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare;
  - (2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw shell EGGS, and meringue; and
  - (3) Raw seed sprouts.
- (D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under §3-301.11(B).
- (E) *Subparagraph (B)(2) of this section does not apply if:*
  - (1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS;*
  - (2) *The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or*
  - (3) *The preparation of the food is conducted under a HACCP PLAN that:*
    - (a) *Identifies the FOOD to be prepared,*
    - (b) *Prohibits contacting READY-TO-EAT FOOD with bare hands,*
    - (c) *Includes specifications and practices that ensure:*
      - (i) **Salmonella Enteritidis** *growth is controlled before and after cooking, and*
      - (ii) **Salmonella Enteritidis** *is destroyed by cooking the EGGS according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*
    - (d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*
      - (i) *Control cross contamination of READY-TO-EAT FOOD with raw EGGS, and*
      - (ii) *Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES, and*
    - (e) *Describes the training program that ensures that the FOOD EMPLOYEE responsible for the preparation of the FOOD understands the procedures to be used.*

## **Chapter 4 Equipment, Utensils and Linens Amendments, Additions, and Deletions**

*Amend § 4-204.111 to revise subparagraph (B)(2) to read as follows:*

### **4-204.111 Vending Machines, Automated Shutoff.\***

- (A) A machine vending POTENTIALLY HAZARDOUS FOOD shall have an automatic control that prevents the machine from vending FOOD:
  - (1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain FOOD temperatures as specified under Chapter 3; and
  - (2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3.
- (B) When the automatic shutoff within a machine vending POTENTIALLY HAZARDOUS FOOD is activated:
  - (1) In a refrigerated VENDING MACHINE, the ambient temperature may not exceed any time/temperature combination as specified under ¶ 3-501.16(A)(2) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or
  - (2) In a hot holding VENDING MACHINE, the ambient temperature may not be less than 57°C (135°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked

*Amend § 4-204.117 to revise the introductory text to read as follows:*

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

A WAREWASHING machine that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be equipped to:

- (A) Automatically dispense detergents and SANITIZERS; and
- (B) Incorporate a visual means to verify that detergents and SANITIZERS are delivered or a visual or audible alarm to signal if the detergents and SANITIZERS are not delivered to the respective washing and SANITIZING cycles.

*Amend § 4-602.11(D) to revise subparagraph (D)(7) to read as follows:*

### **4-602.11 Equipment Food-Contact Surfaces and Utensils.\***

- (D) *Surfaces of UTENSILS and EQUIPMENT contacting POTENTIALLY HAZARDOUS FOOD may be cleaned less frequently than every 4 hours if:*

- (1) *In storage, containers of POTENTIALLY HAZARDOUS FOOD and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*
- (2) *UTENSILS and EQUIPMENT are used to prepare FOOD in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*
  - (a) *The UTENSILS and EQUIPMENT are cleaned at the frequency in the following chart that corresponds to the temperature:*

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

- ; and
- (b) *The cleaning frequency based on the ambient temperature of the refrigerated room or areas is documented in the FOOD ESTABLISHMENT.*
- (3) *Containers in serving situations such as salad bars, delis, and cafeteria lines hold READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same FOOD that is at the required temperature, and the containers are cleaned at least every 24 hours;*
- (4) *TEMPERATURE MEASURING DEVICES are maintained in contact with FOOD, such as when left in a container of deli FOOD or in a roast, held at temperatures specified under Chapter 3;*
- (5) *EQUIPMENT is used for storage of PACKAGED or unPACKAGED FOOD such as a reach-in refrigerator and the EQUIPMENT is cleaned at a frequency necessary to preclude accumulation of soil residues;*
- (6) *The cleaning schedule is APPROVED based on consideration of:*
  - (a) *Characteristics of the EQUIPMENT and its use,*
  - (b) *The type of FOOD involved,*
  - (c) *The amount of FOOD residue accumulation, and*
  - (d) *The temperature at which the FOOD is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*

- (7) *In-use UTENSILS are intermittently stored in a container of water in which the water is maintained at 57°C (135°F) or more and the UTENSILS and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.*

## **Chapter 8 Compliance and Enforcement Amendments, Additions, and Deletions**

*Amend to revise Subpart title for 8-4 to read as follows:*

### ***Applicability and Terms Defined***

#### **8-402 Competency and Access**

*Amend to add § 8-402.10 to read as follows:*

### ***Applicability and Terms Defined***

#### **8-402.10 Competency of Inspectors.**

An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have the knowledge, skills, and ability to adequately perform the required duties.

## **Annex 2 References, 2. BIBLIOGRAPHY, Chapter 3 Amendments, Additions, and Deletions**

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

*Amend References for § 3-501.16 to add new references and redesignate numbering to read as follows:*

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13. Hall, H.E. and R. Angelotti. 1965. *Clostridium perfringens* in meat and meat product. *Applied Microbiology.* 13: 352-354
14. Johnson, K. M., Nelson, C. L. and F. F. Busta. 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of *Bacillus cereus* in a broth model and in rice. *J. Food Sci.* 48: 286-287.
15. Kim, H.U. and J.M. Goepfert. 1971. Occurrence of *Bacillus cereus* in selected dry food products. *J. Milk Food Technol.* 34:12-15.
16. Ladiges, W.C., J.F. Foster and W.M. Ganz. 1974. Incidence and viability of *Clostridium perfringens* in ground beef. *J.Milk Food Technol.* 37(12) 622-623.
17. Lillard, H.S. 1971. Occurance of *Clostridium perfringens* in boiler processing and further processing operations. *J. Food Science.* 36: 1008-1010.
18. Makukutu, C.A. and R.K. Guthrie, 1986. Survival of *Escherichia coli* in food at hot-holding temperatures. *J. Food Prot.* 49(7):496-499.
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<p><b>Annex 3 Public Health Reasons/Administrative Guidelines, Chapter 2 Management and Personnel Ammendments, Additions, and Deletions</b></p>
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**2-301.16 Hand Sanitizers.**

***Amend Public Health Reasons for § 2-301.16 to revise to read as follows:***

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

As a Drug Product

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

A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication **Approved Drug Products with Therapeutic Equivalence Evaluations**. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

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

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2003, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized.

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

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

#### As a Food Additive

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

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

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.
2. A substance may be regulated for the intended use as a food additive under 21 CFR 174 - *Indirect Food Additives - General*, and be listed along with conditions of safe use in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.
3. The intended use of a substance, including substances that contact food such as those in hand sanitizers, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrates that the substance is

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

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCa section 409 (h). Substances that are the subject of an effective food contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Premarket Notifications for Food Contact Substances. This list is available on-line at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>. A food-contact substance that is the subject of an effective notification submitted under FFDCa 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

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

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

**Annex 3 Public Health Reasons/Administrative Guidelines,  
Chapter 3: Food  
Ammendments, Additions, and Deletions**

**3-301.11 Preventing Contamination from Hands.\***

***Amend Public Health Reasons for § 3-301.11 to add the following sentence to the end of the second paragraph under," Clarification of ¶ 3-301.11(B) of the FDA Food Code with Respect to the Phrase "Except... when otherwise APPROVED" :***

Due to the immunocompromised condition of highly susceptible populations, alternatives to the no bare hand contact with ready-to-eat food requirement are prohibited in establishments serving these populations.

### **3-401.11 Raw Animal Foods.\***

***Amend Public Health Reasons for § 3-401.11 to add the following two paragraphs to the end of the introductory text:***

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

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

### **3-501.14 Cooling.\***

***Amend Public Health Reasons for § 3-501.14 to add the following paragraph after the first paragraph of the introductory text:***

The Food Code provision for cooling provides for cooling from 135°F to 41°F or 45°F in 6 hours, with cooling from 135°F to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135°F to 70°F in 1 hour, in which case 5 hours remain for cooling from 70°F to 41°F or 45°F. Conversely, if cooling from 135°F to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70°F took 3 hours, the food safety hazards may not be adequately controlled.

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

***Amend Public Health Reasons for § 3-501.16 to add the following four paragraphs to the end of the section:***

**Hot Holding**

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

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

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

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

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

### **3-502.12 Reduced Oxygen Packaging, Criteria.\***

***Amend Public Health Reasons for § 3-502.12 to add the following paragraph to the end of the section:***

Formation of *Clostridium botulinum* toxin may not be a significant hazard in reduced oxygen packaged products which are properly cooled and frozen immediately after processing, maintained frozen, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important: Keep frozen until used. Thaw under refrigeration immediately before use.")

### **3-603.11 Consumption of Raw or Undercooked Animal Foods.\***

***Amend Public Health Reasons for § 3-603.11 to add the following three paragraphs to the end of the existing text under, "Satisfactory Compliance":***

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

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

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code (Section 3-603.11 in the 1999 FDA Model Food Code)*, March 22, 2000 is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available on the FDA/CFSAN web page at <http://www.cfsan.fda.gov/~dms/fc99guid.html>

**Annex 3 Public Health Reasons/Administrative Guidelines,  
Chapter 4: Equipment, Utensils, and Linens  
Ammendments, Additions, and Deletions**

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

**Amend Public Health Reasons for § 4-501.112 to revise to read as follows:**

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer's specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

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

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

**Amend Public Health Reasons for § 4-703.11 to revise to read as follows:**

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

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

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

**Annex 3 Public Health Reasons/Administrative Guidelines,  
Chapter 8: Poisonous or Toxic Materials  
Amendments, Additions, and Deletions**

*Amend Public Health Reasons to add new § 8-402.10 to read as follows:*

**8-402.10 Competency of Inspectors.**

Regulatory agencies are encouraged to use Standard #2 of the draft *National Voluntary Retail Food Regulatory Program Standards* to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

**Annex 4 Food Establishment Inspection, 3. STAFF  
TRAINING  
Amendments, Additions, and Deletions**

*Amend Public Health Reasons to revise the introductory text to read as follows:*

Basic staff training is very important to staff development and should be a well-defined process. Initial training is usually provided within the local regulatory agency and more advanced training is available through a state agency's program. National training is available from the FDA's Division of Human Resource Development (ORA-U) and the State Training Team, and from the Centers for Disease Control and Prevention's Distance Learning Program. These programs range from basic to advanced subject-specific seminars offered regionally, to home study courses including video, slide, or textbook-based programs, and finally to direct satellite broadcast seminars and courses as a part of the Public Health Training Network.

FDA supports the concept of a competency standard for regulatory professionals and encourages development of education, training and certification criteria consistent with Standard 2 - Trained Regulatory Staff in the draft *National Voluntary Retail Food Regulatory Program Standards*.

There are many components of a valid and credible certification process. Different pre-requisite training and/or testing processes exist for regulators who will be responsible for inspection of foodservice and other retail food establishments. This range of perspectives speaks to the need for criteria that includes consensus support. FDA's draft *National Voluntary Retail Food Program Standards* were developed based on input from regulatory officials, industry professionals, and academia and consumer groups. Standard 2 - Trained Regulatory Staff incorporates an educational curriculum, field training, *Food Code* standardization, and continuing education as minimum criteria for assessing the competency of regulators.

### **Part 3 New Terms for the Index to the Food Code Ammendments, Additions, and Deletions**

- Under Index term, "Consumer," add
  - subheading Advisory,
  - subheading Disclosure,
  - subheading Reminder
- Competency of Inspectors
- Wiping cloths - container storage
- Disclosure
- Reminder