Preface

1. FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS

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

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

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

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

- Improper holding temperatures,
- Inadequate cooking, such as undercooking raw shell eggs,
- Contaminated equipment,
- Food from unsafe sources, and
- Poor personal hygiene

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

Healthy People 2010 and Healthy People 2020 are national initiatives that work through the cooperative federal-state-private sector and which establish 10-year objectives to improve the health of all Americans through prevention. Food Safety Objective 10-6 in Healthy People 2010 is: *Improve food employee behaviors and food preparation practices that directly relate to foodborne illness in retail food establishments.* This includes food operations such as retail food stores, food service establishments, health care facilities, schools and other "food establishments" as defined in the Food Code. In 2010, the Healthy People 2020 objectives will be released along with guidance for achieving the new 10-year targets.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 16 million.

2. PHS MODEL CODES HISTORY, PURPOSE, AND AUTHORITY

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the 20th century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption. Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of

these, which is now titled *Grade A Pasteurized Milk Ordinance – Recommendations of the PHS/FDA,* was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on pp. iii and iv. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

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

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A list of jurisdictions that have reported to FDA their status in adopting the Food Code is available on the FDA CFSAN Web Page at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/ucm108156.htm . The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

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

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part:
"... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (3)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies.

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

3. PUBLIC HEALTH AND CONSUMER EXPECTATIONS

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

Under FDA's 2009 Mission Statement the agency is responsible for:

Protecting the public health by assuring the safety and security of our nation's food supply… and for advancing the public health by helping to make foods safer and more affordable; and helping the public get the accurate, science-based information they need about foods to improve their health.

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

4. ADVANTAGE OF UNIFORM STANDARDS

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

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

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

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model

code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

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

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

5. MODIFICATIONS AND IMPROVEMENTS IN THIS EDITION

The revisions contained in this edition reflect changes, additions, deletions, and format modifications listed in the Supplement to the 2005 FDA Food Code and recommendations developed during the 2008 Biennial meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

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

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

New to the 2009 Food Code is a revised designation system for Code provisions. The former use of "critical" or "non-critical" has been changed in recognition that there is a need for better identifying risk-based controls contained within the Code's provisions.

A Summary of Changes is provided at the end of the Food Code. General enhancements include:

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

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

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

(4) Improved user aids contained in the Annexes such as added references and updated public health reasons, model forms, guides, and lists; and

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

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

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997 (a Third Edition issued June 2001). Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans mandated by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of

controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be potentially hazardous (time/temperature control for safety) and for which retail production would otherwise be prohibited.

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

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

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

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

7. CODE ADOPTION/CERTIFIED COPIES

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

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

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

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

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

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

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food Protection Team, HFS-320, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Refer to item 2. *(A)* of this Preface to access a listing of jurisdictions' adoptions.

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

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

8. INFORMATION TO ASSIST THE USER

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

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4, 5, 6, 7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the Table of Contents together with the Code Reference Sheet (Annex 7, Guide 3-B) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas. The structural nomenclature of the document is as follows:

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

Code provisions are either appropriate for citing and debiting on an inspection report or they are not. Those not intended for citing/debiting are identified by the digits following the decimal point in the numbering system. These "nondebitable" provisions fall into two categories, those that end with two digits after the decimal point and the last digit is a zero, e.g., § 1-201.10; and those that end with three digits after the decimal point and the last 2 digits are zeros, e.g., § 8-805.100.

Two types of internal cross referencing are widely used throughout the Code to eliminate the need for restating provisions.

A. The first type of cross reference uses phrases that contain the word "under", e.g., "as specified **under** … (followed by the relevant portion of the Code)."

   The purpose of this type of cross reference is to:

   1) Alert the reader to relevant information, and

   2) Provide a system by which each violation is recorded under the one most appropriate provision. This type of cross reference signals to the reader the provision of the Code under which a certain violation is properly cited/debited.

B. The second type of cross reference uses phrases that contain the word "in," e.g., "as specified **in**... (followed by the relevant portion of the Code)."

   The purpose of this type of cross reference is to:

   1) Indicate the specific provisions of a separate document such as a federal regulation that are being incorporated by reference in the requirement of the Code, e.g., ¶ 3-201.11(C); or

2) Refer the reader to a nondebitable provision of the Code which provides further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method.

   For example, ¶ 3-201.16 (A) begins with "Except as specified in ¶ (B)…" and ¶ (B) states the relevant exceptions to ¶ (A). Paragraph 3-201.11(E) states in part, "… as specified *in* ¶ 3-401.11(C)" and ¶ 3-401.11(C) provides for an allowance to serve or sell raw or undercooked, whole-meat, intact beef steaks in a ready-to-eat form.

   If you review the exception in ¶ 3-201.16(B) and the allowance in ¶ 3-401.11(C), you will see that exceptions and allowances often contain conditions of compliance, i.e., conditions that must be met in order for the exception or allowance to convey.

Based on the violation being cited, the substance of the text being referred to, and the context in which the reference is made, users of the Code must infer the intent of the cross reference. That is, the user must determine if the cross reference simply alerts the user to additional information about the requirement or if the cross reference:

- sends (via the word "under") the citing/debiting to another Code provision;
  or
- incorporates (via the word "in") the referenced requirements into the Code provision.

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

Portions of some sections are written in *italics.* These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance. Italics are pursuant to a preceding provision that states a requirement, to which the italics offer an exception or another possibility. Italicized sections usually involve the words "except for," "may", "need not" or "does not apply." See ¶ 3-202.18(D).

Requirements contained in the Food Code are presented as being in one of three categories of importance: **PRIORITY ITEM** (i.e. a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that

more directly controls the hazard); **PRIORITY FOUNDATION ITEM** (i.e., a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS); and, **CORE ITEM** (i.e., a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM and that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

A "P" or "Pf" designation after a paragraph or subparagraph indicates that the provision within that section is a PRIORITY ITEM or PRIORITY FOUNDATION ITEM. Any unmarked provisions within a section are CORE ITEMS.

The following conventions are used in the Food Code. "Shall" means the act is imperative, i.e., "shall" constitutes a command. "May not" means absolute prohibition. "May" is permissive and means the act is allowed. The term "means" is followed by a declared fact.

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

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

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

9. THE CODE REVISION PROCESS

(A) Food Code Revision and Publication Cycles

FDA is 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.

(B) Submission of Food Code Change Suggestions

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

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

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

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

10. ACKNOWLEDGMENTS

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