Chapter 1
Introduction and Explanatory Notes

The term "potentially hazardous food" (PHF) was developed by the United States Public Health Service during the last half of the twentieth century to regulate perishable food or drink in eating and drinking establishments (see Appendix A). The current definition of PHF is articulated in the United States Public Health Service/Food and Drug Administration (FDA) Food Code (FDA 1999, p 12)—a model code for adoption by states or counties overseeing operations providing food directly to the consumer. As explained in the Background section of the Charge from FDA, the definition of PHF has become outdated and cumbersome. In particular, the word "hazard" in "potentially hazardous" has implications inconsistent with the use of the word in the Hazard Analysis Critical Control Points (HACCP) concept (NACMCF 1998). The term "rapid and progressive growth" in the FDA Food Code definition is also unclear, especially in the absence of specific information on organisms, media, conditions of growth, or new products with extended shelf life. The need for time/temperature control in foods that traditionally required such control has been eliminated in some instances by new formulations and processes. Moreover, no clear-cut, standardized means are specified in the Food Code to determine whether time/temperature control is needed to ensure the safety of a food.

Many professionals and professional societies involved in food protection share these concerns about the limitations and cumbersome nature of the FDA regulations. For example, the 1996 Conference for Food Protection (CFP) recommended that FDA work with a third party to develop a standard that would address this issue. CFP has also referred the issue to a committee (the Potentially Hazardous Foods Definition Committee) for study. In addition, both the NSF International (NSF) and the American Bakers Association (ABA) are attempting to address these issues by developing protocols to assess the safety of specific foods held at room temperature.

The panel collected and reviewed the criteria and/or definitions that industry, foreign and domestic regulatory agencies, trade organizations, and others currently use to determine whether a food should be stored under controlled time/temperature conditions for safety purposes. Criteria such as pass/fail criteria and challenge tests are included in the scope of this report. In addition, the panel reviewed the common pathogenic microorganisms that are used by industry and organizations in challenge studies to determine whether a food needs time/temperature control for safety. The panel reviewed whether the Food Code term "rapid and progressive growth of microorganisms" is commonly used by industry or organizations,

and how it is applied to determine if a food can be safely stored at room temperature. The panel also evaluated the scientific basis of criteria used to assess growth of common organisms of public health significance.

The panel also discussed the appropriateness of the Food Code definition/term "potentially hazardous," and proposed the use of an alternative or equivalent term, such as "temperature controlled for safety" (TCS). This terminology serves to avoid confusion with the current definition of "hazard" in the Hazards Analysis Critical Control Points (HACCP) approach, and emphasizes the importance of temperature control as a safety factor.

Before any approach to determine whether a food needs time/temperature control for safety can be accepted, an evaluation of its scientific basis is necessary. Thus, the panel conducted an in-depth review of NSF's Standard 75 "International Standard for Non-Potentially Hazardous Foods" (NSF 2000), and ABA's "Industry Protocol for Establishing the Shelf Stability of Pumpkin Pie" (ABA 2000). The panel identified advantages and disadvantages to each organization's approach.

Based on their review and analysis of state, industry, and organization data and protocols, the panel recommended science-based approaches for defining foods that need time/temperature control for safety as well as those that can be excluded from such control. In developing a framework for determining the need for time/temperature control, the panel considered the following criteria: the presence of pathogens on the foods, the characteristics of foods that support growth of pathogens, expected storage conditions, shelf life, and potential storage abuse. The panel developed a science-based framework for determining the effectiveness of processing and/or formulation technologies that result in a food not requiring time/temperature control for safety. The panel reviewed validation techniques that are suitable for determining the effectiveness of these technologies, including process controls, mathematical models, and biological challenge testing. Advantages and disadvantages of each approach are also included in this report.

The panel used their proposed framework to determine its applicability to a specific example(s) from each of the following product categories: salad dressings, condiments such as mustard and mayonnaise, chopped garlic-in-oil, garlic-flavored oil, butter (whipped, not whipped, salted, unsalted), margarine, cheeses, filled bakery products (crème vs. cream), and vegetable breads, such as focaccia.

The panel did not address the following items because they were not included in the FDA charge:

- Issues related to the implementation of a program to verify compliance with the recommended framework. For example, the panel did not identify who the decision-maker should be or how a retail food store inspector would verify whether a product needs time/temperature control.

- Food products that do not require time/temperature control for safety but may be hazardous (that is, cause disease) if they contain pathogenic microorganisms with a low infectious dose were not included in the scope of this report. These are products such as apple cider contaminated with *Escherichia coli* O157:H7. Because the infectious dose of this microbe is low, a low concentration of *E. coli* O157:H7 in food can cause disease. Thus, preventing pathogen growth through time/temperature control would not control the risk.

- Time/temperature control considerations to prevent spoilage.

References

[ABA] American Bakers Association. 2000 Jan 18. Industry protocol for establishing the shelf stability of pumpkin pie [final version plus executive summary]. Washington (DC): ABA. 18 p. Available from: lsanders@americanbakers.org.

[FDA] Food and Drug Administration. 1999. Food Code: 1999 recommendations of the United States Public Health Service, Food and Drug Administration. Springfield (VA): U.S. Dept. of Commerce, Technology Administration, National Technical Information Service. Report nr PB99-115925. Chapter 1, Part 1-201.10(B)(61). p 12. Available from: <http://www.foodsafety.gov/%7Edms/foodcode.html>.

[NACMCF] National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard analysis and critical control point principles and application guidelines. J Food Prot 61:762-75.

[NSF] NSF International. 2000 Nov. 10. Non-potentially hazardous foods. Ann Arbor (MI): NSF International. Report nr ANSI/NSF 75-2000. 12 p.