Chapter 9
Summary and Future Needs

Summary

The panel assembled by IFT was charged with evaluating the Food Code definition of "potentially hazardous foods" and proposing a new framework to determine which foods need time/temperature control for safety. Before critically reviewing the current definition, the panel completed a careful review on how the food safety community, including domestic and foreign government agencies, industry, and other organizations, identify foods that need time/temperature control for safety. In essence, some countries provide a list of foods that should always be time/temperature controlled, unless appropriate information is provided that demonstrates the safety of the specific food when held at ambient temperature. Other countries define foods according to their pH and water activity (a_w) in a manner similar to that of the United States FDA Food Code definition. Some foreign regulatory agencies provide a list of potentially hazardous foods, exempting foods in which specific pH or a_w levels are met. In general, government agencies do not offer a standard procedure by which industry can demonstrate that time/temperature control requirements are not necessary. For instance, the regulations and guidelines of these various agencies include no mention of specific protocols for microbial challenge studies or microbial growth modeling programs that could aid in supporting a decision to store a food at ambient temperature.

In the United States, most states have adopted the Food Code definition of potentially hazardous foods. This definition relies solely on pH and a_w as the parameters for making decisions about the need for time/temperature control for safety. After an in-depth evaluation, the panel concluded that revisions are needed in order for the Food Code description to be meaningful and accurate in identifying foods that require time/temperature control. These reconsiderations are particularly important in light of the novelty and complexity of currently available foods along with the additional knowledge and scientific information gained in recent years.

The panel conducted a survey among industry and other organizations to gain knowledge on how food product manufacturers are tackling this issue. Data collected from the industry survey clearly show that some products currently identified as potentially hazardous foods could be stored at ambient temperature by virtue of the process method, formulation, time of storage, or other characteristics of the food. In most

cases, microbial challenge studies were used to support such conclusions. In the absence of practical standardized protocols for applying the current definition to foods, two organizations, NSF International and American Bakers Association (ABA), developed protocols. Although not yet officially implemented, the NSF International and ABA protocols are being followed by some laboratories and companies as a guide to determine the time/temperature control status of a food. The panel concluded that both protocols present significant weaknesses in their approach to defining foods that do not need time/temperature control for safety. The data from the industry survey, the absence of a robust standardized method, and the experience of the panel further indicated that the current FDA Food Code definition needs to be revisited.

The panel developed a framework that would accurately identify which food products need time/temperature control. Several general approaches were proposed, reviewed, and critiqued by panel subgroups. Microbial growth factors that would affect the need for time/temperature control were discussed at length, including product history of safe use and processing methods (see Chapter 3). To critically evaluate pH and a_w values and their interactions, the panel reviewed in-depth microbial growth data from the scientific literature. Data obtained through validated predictive microbial growth models were used to confirm the panel's determinations.

The panel concluded that although research demonstrates that parameters such as packaging environment, antimicrobials, nutrient content, or competitive microflora influence growth of microbial pathogens, sufficient data to specify the limits of such parameters are not yet available. Therefore, specific criteria used in the framework were limited to a_w, pH, and their interaction. Although pH and a_w were the only criteria for which scientific-based values could be provided, the effects of many other parameters are addressed in subsequent steps in the framework. For instance, the panel recognized that historically, certain foods, such as white bread, have been safely stored at ambient temperatures. The panel provided a framework in which foods with scientific rationale that could justify such a safe history of use could continue to be stored and/or used at ambient temperatures.

The method used to process a food is another important factor considered in the proposed framework. The panel's framework indicates, for instance, that if a food has been processed to eliminate all vegetative pathogens (for example, with a properly validated heat or high hydrostatic pressure method) and packaged to avoid post-process contamination, only pathogenic spore-forming microorganisms would be of public health concern. This factor was handled in the framework by developing different critical pH/a_w limits, depending on whether spores or vegetative cells and spores are the likely hazards. In cases where

the a_w and pH combination suggests the food needs time/temperature control for safety, a product assessment can be performed to make a more definite decision. Such a food product assessment may involve a detailed description of the product characteristics, such as antimicrobials or packaging environment that may support a history of safe use at ambient temperatures. On the basis of safe use and a reliable product assessment, a product may be regarded as safe at ambient temperature.

Alternatively, a validated in-house food-specific microbial growth model may be appropriately used to decide whether a food needs time/temperature control. Validation of these models is essential because many microbial growth models have been developed from data generated in media, and an extrapolation of those data to real food situations may not be appropriate. These models developed with media data may still be useful in selecting microorganisms for microbial challenge studies or limiting food parameters; if, however, after product assessment and/or microbial growth modeling a clear decision cannot be made, microbial challenge studies may provide the definite data to determine whether a food requires time/temperature for safety.

The panel described in detail the issues to be considered when designing challenge studies and interpreting data. In addition, pass/fail criteria for challenge tests were determined based on limited pathogen growth or toxin formation. The panel recognized that it was appropriate to develop different criteria for each pathogen because infectious doses and typical contamination levels vary for different pathogens. To critique their framework, the panel selected and assessed a list of food products.

In summary, the panel introduced a new approach for evaluating foods that may need time/temperature control for safety. This framework was based solely on scientific data from peer-reviewed publications that were further evaluated by the panel. The panel recognizes that the implementation of their approach in the field may not be an easy task. For example, although some of the considerations introduced in the proposed framework require careful evaluation and assessment by an expert microbiologist, this report does not attempt to propose who would be responsible for deciding the time/temperature status of a food. The panel also did not address the implications of the framework at the retail level. The panel believes, however, that in light of the complexity of the food systems and the confusion over the interpretation of the term “potentially hazardous foods,” a science-based framework such as the one proposed here would be a more accurate, comprehensible, and clear alternative to the current definition and application of the term.

Future Needs

- Validate the framework for a broad variety of products, including those that are presently handled as TCS but have the potential to be non-TCS or are presently handled as non-TCS and may be TCS. Products from various sources should be used for framework validation.

- Develop educational and other required programs for implementing a validated TCS food framework at the federal, state, and local level.

- Develop general predictive models that include the effects of several parameters, such as packaging atmosphere, redox potential, a_w, pH, and selected ingredients, on the growth of pathogens of concern.

- Identify and validate appropriate pathogen and/or surrogate strains for use in challenge studies in different groups of foods.

- Investigate synergistic inhibitory effects of various strategies that combine more than one antimicrobial control parameter (hurdle technologies) as they relate to non-TCS foods.

- Identify improved methods for detection of *Clostridium botulinum*, *Staphylococcus aureus*, and *Bacillus cereus* toxins for evaluating the need for time/temperature control of foods.

- Validate the appropriateness of test frequency and method sensitivity as they relate to pathogen growth and pass/fail criteria for TCS foods;

- Collect epidemiological data to support the anecdotal evidence on safe or unsafe history of use for foods that may be considered TCS or non-TCS. Establish the scientific explanations for their safe or unsafe use.

- Determine the effect of alternative processing technologies on human pathogens in the production of non-TCS foods.

- Establish Food Safety Objectives for the production of non-TCS and TCS foods that may have potential to be non-TCS. Determine the performance criteria and process criteria for these systems.

- Develop methods, approaches, and frameworks to evaluate shelf life open-dating for safety.

- Identify specific factors that control pathogen growth in products that appear to be TCS foods but do not support growth of the pathogens when challenged.

- Establish accurate measurement techniques for intrinsic and extrinsic factors in food microenvironments and interfaces in multicomponent foods. Determine with accurate and sensitive analytical methods the effects of these microenvironments and interfaces on microbial responses.