Evaluation and Definition of Potentially Hazardous Foods

A Report of the Institute of Food Technologists
for the Food and Drug Administration
of the U.S. Department of Health and Human Services

December 31, 2001

IFT/FDA Contract No. 223-98-2333
Task Order No. 4

Table of Contents

Preface
Acknowledgments
Science Advisory Board
Scientific and Technical Panel
Reviewers
Additional Acknowledgments
IFT/FDA Task Order Charge
Background
Current Policy
Scope of Work
Executive Summary
Chapter 1. Introduction and Explanatory Notes
References
Chapter 2. Current and Proposed Definitions of "Potentially Hazardous Foods"
1. Regulations review
1.1 Food and Drug Administration
1.2 United States Department of Agriculture (USDA)
1.3 State Regulations
1.4 International Regulations
2. Critique of FDA's "potentially hazardous foods" definition
References

Chapter 3. Factors that Influence Microbial Growth
1. Introduction
2. Intrinsic factors
2.1 Moisture content
2.2 pH and acidity
2.3 Nutrient content
2.4 Biological structure
2.5 Redox potential
2.6 Naturally occurring and added antimicrobials
2.7 Competitive microflora
3. Extrinsic factors
3.1 Types of packaging/atmospheres
3.2 Effect of time/temperature conditions on microbial growth
3.3 Storage/holding conditions
3.4 Processing steps
4.0 Other factors
4.1 Intended end-use of product
4.2 Product history and traditional use
4.3 Interactions of factors
References

Chapter 4. Analysis of Microbial Hazards Related to Time/Temperature Control of Foods for Safety

1. Introduction
2. Meat and poultry products
3. Fish and seafood products
4. Fruits and vegetables
5. Cereal and grains and related products
6. Fats, oils, and salad dressings
7. Butter and margarine
8. Sugars and syrups
9. Eggs and egg products
10. Milk and milk products (except cheeses)
11. Cheeses
12. Combination products

References

Chapter 5. Effect of Preservation Technologies and Microbiological Inactivation in Foods

1. Introduction
2. Validation of processing parameters
3. Processing technologies

3.1 Water activity and pH
3.2 Technologies based on thermal effects
3.3 High pressure processing
3.4 Pulsed electric fields
3.5 Irradiation
3.6 Other technologies

References

Chapter 6. Microbiological Challenge Testing

1. Introduction
2. Selection of challenge organisms
3. Inoculum level
4. Inoculum preparation and method of inoculation
5. Duration of the study
6. Formulation factors and storage conditions
7. Sample analysis
8. Data interpretation
9. Pass/Fail criteria

References

Chapter 7. Comparion of NSF and ABA Protocols to Determine Whether a Food Requires Time/Temperature for Safety

1. Introduction
2. Consideration of process
3. Microorganisms
4. Pass/fail criteria
5. Number of sampling times
6. Replication
7. Oxidation-reduction potential
8. Methodology

9. Inoculum position
10. Duration of test
11. Product categories
12. Summary
References

Chapter 8. Framework Developed to Determine Whether Foods Need Time/Temperature Control for Safety
1. Description of framework
2. Framework
3. Critique of framework. Application of framework to foods

Chapter 9 Summary and Future Needs

Appendices
Appendix A. Development of the Definition of "Potentially Hazardous Foods"
Appendix B. Data from Industry and Trade Organizations
Appendix C. Scientific Data Used to Develop the Framework
Appendix D. Industry Protocol for Establishing the Shelf Stability of Pumpkin Pie American Bakers Association
Appendix E. Non-Potentially Hazardous Foods. American National Standard/NSF International Standard

List of References

PREFACE

On September 30, 1998, the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services signed a five-year contract with the Institute of Food Technologists (IFT) to provide scientific review and analysis of issues in food safety, food processing, and human health. Under the terms of the contract, FDA assigns IFT task orders, categorized as comprehensive or abbreviated reviews. IFT assembles Scientific and Technical Panels comprised of experts in the topic area to address the issues. The panels are charged with providing scientific and technical review and analysis, not with setting policy.

This report is IFT's response to Task Order No. 4: Analysis and Definition of Potentially Hazardous Foods. The Background and Scope of Work that FDA provided to IFT are included. In October 2000, IFT assembled a Scientific and Technical Panel. This panel was comprised of experts in food safety and microbiology, including safety in food retail, food service, regulatory affairs, and risk analysis. The panel met in person and via conference calls throughout the year 2000. IFT also assembled a Science Advisory Board to

advise IFT on the FDA contract and on the individual task orders.

The Institute of Food Technologists greatly appreciates the efforts of the Scientific and Technical Panels, the Science Advisory Board, the many reviewers, staff and others who made this report possible. Compensation for such an effort pales in comparison to the time, effort and expertise expended.

IFT is especially grateful to the FDA staff for their tremendous cooperation, communication, and assistance at every stage of this project. IFT submits this report to the Agency to contribute to the assessment and development of an operational science-based system to address foods that may require time/temperature control for safety reasons.

SCIENCE ADVISORY BOARD

Roy G. Arnold, Ph.D.
Executive Associate Dean
College of Agricultural Science
Oregon State University

Lester M. Crawford, Ph.D., D.V.M.
Director
Center for Food and Nutrition Policy
Virginia Polytechnic Institute and State University

Ray A. Goldberg
George M. Moffett Professor of Agriculture
and Business Emeritus
Harvard Business School

Marcus Karel, Ph.D.
Professor Emeritus
Massachusetts Institute of Technology
and Rutgers University

Sanford A. Miller, Ph.D.
Adjunct Professor
Center for Food and Nutrition Policy
Virginia Polytechnic Institute and State University

Martha Rhodes Roberts, Ph.D.
Deputy Commissioner for Food Safety
Dept. of Agriculture
and Consumer Services State of Florida

G. Edward Schuh, Ph.D.
Freeman Chair Professor
Hubert H. Humphrey Institute of Public Affairs
University of Minnesota

Barbara O. Schneeman, Ph.D.
Professor of Nutrition
Department of Nutrition
University of California

INSTITUTE OF FOOD TECHNOLOGISTS
Scientific and Technical Panel

Frank F. Busta, Ph.D.
Panel Chair and Senior Science Advisor to the Institute of Food Technologists
University of Minnesota

Dane T. Bernard, Ph.D.
Keystone Foods

Robert B. Gravani, Ph.D.
Cornell University

Paul Hall
Kraft Foods, Inc.

Merle D. Pierson, Ph.D.
Virginia Polytechnic Institute

and State University

Gale Prince
The Kroger Company

Donald W. Schaffner, Ph.D.
Cook College Rutgers
The State University of New Jersey

Katherine M.J. Swanson, Ph.D.
The Pillsbury Company

Betsy Woodward
Food Labs for Florida Department of Agriculture
and Consumer Services (Retired Chief)

Frank Yiannas
Food Safety and Health
Walt Disney World

REVIEWERS

Catherine Adams, Ph.D.
Heinz North America

Michael H. Brodsky
Brodsky Consultants

Alfred E. Bugenhagen
New York Department
of Agriculture and Markets

Martin Cole
Food Australia

J. Joseph Corby
New York State Department
of Agriculture and Markets

Carl S. Custer
U.S. Dept. of Agriculture

Michael P. Davidson, Ph.D.
University of Tennessee

Robert Donofrio
NSF International

Michael P. Doyle, Ph.D.
University of Georgia

Russell S. Flowers, Ph.D.
Silliker Labs Group, Inc.

Leonard Wm. Heflich
Bestfoods Baking Company

Leon Gorris
Uniliver

Maureen Olewnik
American Institute of Baking

Virginia N. Scott
National Food Processors Association

John Silliker, Ph.D.
Silliker Labs, Inc.

George Smith
Arkansas Department of Health

Pete Snyder
Hospitality Institute of Technology
and Management

Dan Sowards
Texas Department of Health
Food Safety

William H. Sperber
Cargill, Inc.

Bruce Tompkin
Armour Swift-Eckrich

Edmund A. Zottola, Ph.D.
University of Minnesota

ADDITIONAL ACKNOWLEDGMENTS

Food and Drug Administration

Donald M. Kautter, Jr.
Contract Technical Officer
Division of HACCP Programs

Ed Arnold
Contracting Officer

Jeanette Lyon
Consumer Safety Officer
Retail Food and Interstate Travel Team

Institute of Food Technologists

Bruce R. Stillings, Ph.D.
1998-1999 President

Charles E. Manley, Ph.D.
1999-2000 President

Mary K. Schmidl, Ph.D.
2000-2001 President

Phillip E. Nelson, Ph.D.
2001-2002 President

Mark McLellan, Ph.D.
2002-2003 President Elect

Daniel E. Weber
Executive Vice President
Fred R. Shank, Ph.D.
Vice President, Science, Communications
and Government Relations

Jill A. Snowdon, Ph.D.
Director, Department of Science
and Technology Projects

Maria P. Oria, Ph.D.
Staff Scientist

Karen Arcamonte, M.S.

Information Specialist

Kendra Langeteig, Ph.D.
Administrative Assistant

Other Contributors

The Institute of Food Technologists and the Science and Technology Expert Panel express their thanks to the many companies and trade associations that cooperated with this project by sharing research data. While remaining as confidential information to all participants, the data was of great value to this report and we appreciate the efforts of those companies and individuals. In addition, the Institute and the panel appreciate the cooperation of the state governments that, by submitting data and information, contributed to the quality of this report.

Background (Provided by FDA to IFT)

The June 1940 and 1943 recommendations of the Public Health Service (PHS) for eating and drinking establishments used the term "readily perishable food and drink." The "Food Service Sanitation Manual," issued in 1962 by the PHS first defined the term "potentially hazardous food" (PHF) as any perishable food which consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, or other ingredients capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms. "Perishable Food" was defined as any food of such type or in such condition as may spoil. The 1976 Food Service Sanitation Manual expanded the 1962 PHF definition to include edible crustacea, and food containing synthetic ingredients. Both the 1976 Food Service Sanitation Manual and the 1982 Retail Food Store Sanitation Code clarified that the food must be in a form capable of supporting rapid and progressive growth, and excluded from the definition foods that have a pH level of 4.6 or below; a water activity of 0.85 or less under standard conditions; clean, whole, uncracked, odor-free shell eggs; and food products in hermetically sealed containers processed to prevent spoilage. Whole, shell eggs were later included in the definition of PHF via an interpretation, and subsequently included in the 1993 Food Code definition.

With the advent of the Hazard Analysis Critical Control Point (HACCP) approach to food safety, the root word "hazard" in "potentially hazardous" became inconsistent with the use of the term hazard in HACCP. If an uncontrolled food safety hazard exists, the food is not potentially hazardous; but it *is* hazardous.

Furthermore, scientific understanding and legal enforcement of the term "rapid and progressive growth" was unclear. Scientists questioned what the term really meant out of context, i.e., without a given organism, medium, or conditions of growth. The issue became extremely important when FDA attempted to deal with industry requests to allow pumpkin pies to be stored at room temperature during display at retail.

Beginning in the late 1980's, the Food and Drug Administration (FDA) was asked to respond to requests from food processors and manufacturers to evaluate foods which were traditionally considered to be potentially hazardous (requiring time/temperature control) but which were formulated to be nonpotentially hazardous. This end-product condition was achieved not by manipulating the pH or water activity alone, but through a combination of pH or water activity and processing methods or preservatives, and the product was intended to be displayed for sale at room temperature. The vast majority of these requests related to the display of pies, usually pumpkin or sweet potato, for which the pH and water activity were adjusted and preservatives added to control the growth of pathogenic organisms. Other food categories for which FDA is questioned include 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), stuffed breads such as focaccio.

The FDA reviewed these requests regarding pumpkin pies, evaluated challenge studies, and issued opinions allowing or disallowing the display or sale of these pies at ambient temperature, based on the Food Code definition of potentially hazardous food. Although the FDA reviewed the data based on the pathogen of concern for each product, written, specific criteria for the challenge testing were lacking. There is a need for such criteria and for on-site verification that the products are manufactured as claimed. This concern was discussed at the 1996 Conference for Food Protection (CFP) meeting and the CFP subsequently recommended that FDA work with a third party to develop a standard that would address the issue.

In August 1996, NSF International Inc. (NSF), an American National Standards Institute (ANSI)–accredited organization, decided to develop a standard that would address these requests by industry and sought the FDA's participation in a Joint Committee to create new NSF Standard #75, Nonpotentially Hazardous Foods. The FDA has participated in the development of the draft Standard. Draft Standard #75 is being pilot tested by NSF and the document is available for review.

This draft Standard includes a protocol to determine if a food meets the Food Code definition of potentially hazardous. That protocol calls for subjecting the food to predescribed laboratory testing and sets forth the lab methods including inoculation procedures, organisms to be tested, and pass/fail criteria for defining rapid and progressive growth.

In February 2000, the American Bakers' Association (ABA) presented to FDA for review its Protocol for Establishing the Shelf Stability of Pumpkin Pie, a voluntary industry program for manufacturing pumpkin pies to be retailed without refrigeration. ABA based its protocol on the assumption that a pie that is cooked adequately, cooled promptly, and packaged, while minimizing the opportunity for contamination after cooking, is nonpotentially hazardous because pathogens are absent after cooking. It does not address an inoculation or microbial testing protocol. Defining "rapid and progressive growth" is a non-issue under the ABA protocol, since controls are based on industry research that shows that surviving spore formers, after cooking, cannot grow due to barriers in the pie formulation.

Current Policy

FDA's current policy is reflected in the 1999 Food Code, Paragraph 1-201.10 (B) (61) definition of "potentially hazardous food" that describes food that requires temperature control as one that supports the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of *Clostridium botulinum*, or, in raw shell eggs, the growth of *Salmonella Enteritidis*. The definition further describes types of foods that are and are not included. Recognizing the need to update and revise the definition, FDA submitted an Issue to the 2000 CFP meeting, asking CFP to address the proposal. CFP referred the Issue to committee for study.

In the CFP Issue, FDA stated that modern food technology makes the determination of whether a food is a PHF very difficult. There is no standardized methodology for what constitutes "laboratory evidence." There are concerns about the slow growth (as opposed to "rapid and progressive growth") of low-dose pathogens in food. Foods that have been historically recognized as not being PHF are now in question, particularly produce items such as lettuce and tomatoes. Foods that are PHF are known to have caused human illness because pathogens are able to grow and multiply to levels that cause infections in humans or produce toxins in the food. Such microbiological hazards must be controlled through the application of critical limits for pH, a_W, time, and temperature.

The FDA's proposed new definition defines the acceptance criterion for a PHF as being less than a 1 log increase of a pathogen when the food is stored at 24 °C (75 °F) for a period of time that is 1.3 times the shelf life as determined by the manufacturer.

The temperature of 24 °C (75 °F) was selected because it is a temperature at which mesophyllic and psychrotrophic pathogens will demonstrate growth and is commonly used for testing in laboratory settings.

The time frame of 1.3 times the expected shelf life is to allow a reasonable period for storage at the food establishment and at home following purchase. The National Institute for Standards and Technology (NIST) Handbook 130 considers a "reasonable period for consumption to be one-third the approximate total shelf-life of the perishable food." Reference: NIST, Handbook 130, 1998 Edition issued November 1997.

In determining whether a food supports microbial growth, FDA believes that the whole food, its individual components, and interfaces of components must be tested. Individual components, such as toppings or fillings, may have significantly different pH or water activity levels and each needs to be evaluated to determine if it is capable of supporting growth.

FDA's use of the term "potentially hazardous food" is intended to define food that must be kept cold or hot because the food has the necessary intrinsic factors to SUPPORT THE GROWTH of pathogens. The two terms do not imply whether or not the foods have initial loads of bacteria, become contaminated with bacteria, or are adulterated.

Scope of Work (As Assigned by FDA to IFT)

Independently, and not as an agent of the Government, the Contractor shall furnish the necessary materials, services, facilities, and otherwise do all things necessary for or incidental to the performance of the work set forth herein.

The Contractor shall review the scientific literature, shall consult with academic experts, and shall consider the requirements of other governmental bodies to address the following specific questions:

1. The Contractor shall review what criteria or definitions are used by industry, trade organizations, regulatory bodies (foreign and domestic) and others to determine which foods must be temperature-controlled for safety, including pass/fail criteria that are used, organisms of public health significance

that are used as indicators, and whether the term "rapid and progressive growth" is used. What is/are the scientific basis/criteria used for such determinations? The Contractor shall evaluate the validity of the scientific basis upon which those criteria or definitions are based. Are there alternative words or phrases that are used by industry, trade groups, and others in lieu of the term "potentially hazardous"?

2. The Contractor shall do an in-depth review of the 2 approaches previously outlined in the Background (NSF and ABA) plus other possible alternative approaches and protocols that address potentially hazardous foods. Describe the advantages and disadvantages of each approach.

3. Based on the information obtained for Items 1 and 2, the Contractor shall provide evaluations and recommendations as to the best science-based framework for defining foods that need time/temperature control(s) for safety. The Contractor shall evaluate and provide options that may be used in addressing foods that should be included in the definition (foods that need time/temperature controls for safety) and foods that should be excluded; incorporating information on whether the food matrix supports growth, pathogenic organisms that are associated with the specific foods, expected storage conditions, shelf life, and potential storage abuse.

4. Based on the information obtained for Items 1 and 2, the Contractor shall review, evaluate and provide recommendations as to the best science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is nonpotentially hazardous. Are processing technologies or mathematical models sufficient, or are biological challenge tests needed, and why? Describe the advantages and disadvantages of each approach considered. For approaches that rely on microbiological challenge testing, the Contractor shall review and evaluate what indicator organism(s) and laboratory testing procedures can be used to validate that a food or food commodity is not potentially hazardous.

5. The Contractor shall demonstrate and critique the systems and frameworks developed by the contractor for Items 1, 2, 3, and 4 by applying them to the following list of food groups in order to determine whether the foods are or are not potentially hazardous and the justification as to the conclusion:
    - 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)
- Vegetable-stuffed breads, such as focaccio

Executive Summary

The current definition of "potentially hazardous foods" (PHF) is articulated in the United States Public Health Service/Food and Drug Administration (FDA) Food Code—a model code for adoption by states or counties overseeing operations providing food directly to the consumer. Many professionals and professional societies involved in food protection share concerns about the limitations and cumbersome nature of the FDA regulations. Both the NSF International (NSF) and the American Bakers Association (ABA) are attempting to address some of these issues by developing protocols to assess the safety of specific types of food held at ambient temperature. In light of these issues, an IFT panel of experts was charged by FDA to review the current Food Code definition and propose a framework to determine if, based on scientific information, a food needs time/temperature for safety. The panel did not address the following items in the report because they were not included in the FDA charge: issues related to policy and implementation of the proposed framework; food products that do not require time/temperature control for safety but may be hazardous if they contain pathogens with a low infectious dose; and time/temperature control considerations to prevent spoilage.

Definitions. The IFT panel searched domestic and international regulations and guidelines for terms similar to PHF and associated requirements. Most states have adopted the FDA Food Code definition of PHF. The U.S. Department of Agriculture identifies criteria for shelf-stable products, such as Moisture Protein Ratio, pH, or a_w. Australia, Canada, and the United States use the term PHF in their food safety regulations. Other regulatory entities have temperature control requirements, but do not use the term PHF. While temperature requirements for chilled foods are identified, other regulations for temperature control generally do not present guidelines or a framework to determine which foods fall into the "chilled" category. Rather, specific reference is made to the need of temperature control to protect public health. Some products that need to be temperature controlled for safety are identified. These products generally have a history of association with illness in the absence of temperature control.

It is the opinion of the panel that the current FDA Food Code definition of PHF foods is complex and causes some in the food safety community to limit consideration of factors to only pH and a_W. This limitation results in the inclusion of many foods as PHF when, in fact, they are not. Many foods that meet the current definition can be hazardous if pathogens are present at infectious levels. Conversely, many products with pH and a_W above the levels identified in the current Food Code definition have been safely stored at ambient temperatures (for example, white bread, certain cheese spreads, some fermented sausages) due to other science-based reasons. Control of all relevant pathogens must be addressed and

should not be restricted to *Clostridium botulinum* and *Salmonella* Enteritidis. The term "rapid and progressive" in Section a in the Food Code is no longer appropriate. Current production, processing and packaging technologies, extended shelf life products, distribution systems, and consumer-use practices have altered this paradigm. Pathogen growth need not be rapid but only progressive; the amount of growth that may present a hazard is specific to the organism, the food, and other factors. "Scientific evidence" to determine whether a food needs time/temperature for safety should include laboratory and modeling evidence, and literature.

The panel recommends the development of a simplified definition, with an interpretive guide, to strengthen the regulatory focus on appropriate foods by 1) providing detailed, scientifically based examples of products that can be stored safely without temperature control; and 2) avoiding misclassification of safe foods. The agency might consider adopting a term for defining foods that require time/temperature control for safety such as "temperature controlled for safety" (TCS). This term accurately describes both what is required—temperature control with time implied—and why it is required—safety. A definition of TCS foods might be considered such as "foods that require time/ temperature control to limit pathogen growth or toxin formation that constitutes a threat to public health."

Factors that influence microbial growth. The need for time/temperature control is primarily determined by 1) the potential for contamination with and survival of pathogenic microorganisms of concern, and 2) the potential for subsequent growth and/or toxin production. The following list of factors may be considered when determining whether a food requires time/temperature control during storage, distribution, and handling at retail and in food service to assure consumer protection. Care should be taken when analyzing multicomponents foods because measurements of pH, redox potential, antimicrobials, or a_w may not reflect the actual value in a microenvironment or at the interface among the different components. In these cases, the parameters should be measured at the interface areas of the food, as well as in any potential microenvironment.

Moisture content. The water requirements of microorganisms are defined in terms of the water activity (a_W) of the food or environment. The a_W of a food describes, among other [factors?], the availability of water to facilitate growth of microorganisms. In foods, it ranges from 1.00 (for example, meats) to 0.1 (for example, crackers). The a_W can be manipulated in foods by a number of means, including addition of solutes, physical removal of water, or binding of water to various macromolecular components in the food. Microorganisms generally have optimum and minimum levels of a_W for growth depending on other growth factors in their environments, such as the solute. Also, a_w may be used in combination with other factors to control pathogens in certain food products.

pH and acidity. Increasing the acidity of foods, either through fermentation or the addition of weak acids, has been used as a preservation method since ancient times. Most foods such as meat, fish, and vegetables are slightly acidic, while most fruits are moderately acidic. A few foods such as egg white are alkaline. Organic acids are more effective as preservatives in the undissociated state. Buffering capacity also must be considered. For certain foods, titratable acidity is a better measure of the microbiological stability. It is well known that groups of microorganisms have pH optimum, minimum, and maximum for growth in foods. The pH can interact with other factors such as $a_{w,}$ salt, temperature, redox potential, and preservatives to inhibit growth of pathogens and other organisms. Based on a comprehensive review of the literature, the panel concluded that a pH of 4.6 is appropriate to control spore-forming pathogens, and a pH of 4.2 is appropriate to control vegetative pathogens.

Nutrient content. The abundance of nutrients in most foods is sufficient to support the growth of a wide range of foodborne pathogens.

Biological structure. Plant and animal derived foods have biological structures that may prevent the entry and growth of pathogenic microorganisms. Several factors may influence penetration of these barriers and potentially allow the growth of microbial pathogens.

Redox potential. Redox potential is a measurement of the ease by which a substance gains or loses electrons. Eh for growth of aerobes is +500 to +300 mV; facultative anaerobes is +300 to –100 mV; and anaerobes is +100 to less than –250 mV. Values of Eh for foods can be highly variable. Although Eh measurements could possibly be used in combination with other factors to evaluate the potential for pathogen growth, limitations such as low accuracy of measurements make it a rather difficult and variable factor that could result in erroneous conclusions.

Antimicrobials. [Antimicrobials include] Naturally-occurring plant-based antimicrobial (for example, essential oils, tannins, glycosides) and animal-based antimicrobials (for example, lactoferrin, lysozyme). Some food processing forms antimicrobial compounds (for example, Maillard compounds, smoke condensates, bacteriocins). In addition, a variety of chemical preservatives and additives can extend the shelf life of food and/or inhibit pathogens, either singly or in combination. Added antimicrobial compounds can have an interactive or synergistic inhibitory effect with other parameters of the formulation, such as pH, a_W, presence of other preservatives, types of food constituents, presence of certain enzymes, processing temperature, storage atmosphere, and partition coefficients.

Competitive microflora. Metabolic products produced by microorganisms growing in food may limit (by antagonistic interactions) or induce (by synergistic interactions) the growth of particular species, creating an association or succession. Dominance of particular metabolically active organisms occurs as a dynamic process. Antagonistic processes usually include competition for nutrients, competition for attachment/adhesion sites (space), unfavorable alterations of the environment, or a combination of these

factors. Growth stimulating mechanisms also exist and must be considered when the hurdle concept is used to control microorganisms in temperature-sensitive foods.

Atmosphere. Gases inhibit microorganisms by two mechanisms: direct toxic effects that can inhibit growth and proliferation (carbon dioxide, ozone, and oxygen), or modification of the gas composition, which has indirect inhibitory effects by altering the ecology of the microbial environment (nitrogen). Atmospheres that have a negative effect on the growth of one particular microorganism may promote the growth of another. Technologies used to inhibit the growth of microorganisms include modified atmosphere packing (MAP), controlled atmosphere packaging (CAP), controlled atmosphere storage (CAS), direct addition of carbon dioxide (DAC), and hypobaric storage.

The major safety concern in extending shelf life of foods by MAP or related technologies is the loss of sensory cues to spoilage provided by bacterial growth, that is, a food could have acceptable organoleptic quality, but be unsafe. By combining antimicrobial atmospheres with other techniques, hurdle technology strategies may be generated that can further enhance food quality and safety.

Time/temperature. Time parameters define the growth of a microorganism and, consequently, determine a product's microbial shelf life and safety. Shelf life is the time period from when the product is produced until the time it is intended to be consumed or used. Several factors determine shelf life, ranging from organoleptic qualities to microbiological safety. For the purpose of this report, the key consideration is the microbiological safety of the product. Under certain circumstances, time alone at ambient temperatures can be used to control product safety. When time alone is used as a control, the duration should be equal to or less than the lag phase of the pathogen(s) of concern in the product in question. The lag time and generation time of a microorganism depend on temperature; therefore, for a specific food product, the shelf life or use period required for safety may vary depending on the temperature at which the product is stored.

Microorganisms have a minimum, maximum, and optimum temperature for growth and/or toxin production. Temperature has a dramatic impact on both the generation time of an organism and its lag period. Growth rate increases with increasing temperature up to the optimum, thereafter declining rapidly, until the temperature maximum is reached. The relationship between temperature and growth rate varies significantly across groups of microorganisms. The lag period and growth rate of a microorganism are influenced not only by temperature but by other intrinsic and extrinsic factors as well.

Storage and holding conditions. Some key factors addressed were storage/holding temperature, the time/temperature involved in cooling of cooked items, and the relative humidity to which the food or packaging material may be exposed. Time and temperature are integral and must be considered together. Foods that have been cooked or re-heated and are served or held hot may require appropriate time/temperature control for safety. Cooling food too slowly may permit growth of spore-forming

pathogens. Consequently, for certain foods specific times and temperatures for rapid cooling are prescribed for safety.

The relative humidity of the storage environment may alter the a_w of the food. Foods that depend on a certain a_w for safety need to be stored in an environment that does not markedly change this characteristic. Product should be held under conditions where the environment does not alter the a_w of the product in an unfavorable way.

Processing steps. Low-acid canned foods in a hermetically sealed container do not require temperature control for safety. However, less processed foods in less robust packaging, for example a baked product cooled and packaged under conditions that do not allow recontamination, may be safe and stable at room temperature until consumed. Scientifically sound criteria for determining whether foods require time/temperature control for safety should consider 1) processes that destroy vegetative cells but not spores (when product formulation is capable of inhibiting spore germination); 2) post-process handling and packaging conditions that prevent reintroduction of vegetative pathogens onto or into the product before packaging; and 3) the use of packaging materials that while they do not provide a hermetic seal, do prevent reintroduction of vegetative pathogens into the product.

Intended end-use. A food product that does not require time/temperature control for safety at one point in the food production may require such control at another point, depending on its intended use. For example, a thermally processed food that is hot-filled into its final packaging may not require refrigeration if spore-forming pathogens are not capable of outgrowth but may require refrigeration once the food item is removed from its original packaging.

Product history. There are foods, such as white bread, that have a long history of safe storage use at ambient temperatures yet have formulations, pH, and a_w that would designate them as TCS foods. For a product to be identified as non-TCS based on history and traditional use, the intrinsic and extrinsic factors affecting microbial growth need to have been and remain constant. Product history, alone, should not be used as the sole factor in determining whether or not a food needs time/temperature control for safety, unless a valid scientific rationale is provided.

Interaction of factors. Although there is a long-standing recognition of interactions and the hurdle technology effect of inhibitory factors, the current definition of "potentially hazardous foods" considers pH and a_w only as individual independent factors. The panel believes that pH and a_W interactions must also be taken into consideration. Models that address pH/a_W interaction are available. Models including other factors such as atmosphere and preservatives have also been published. However, a general model for foods that covers all of these interactions does not currently exist. Nevertheless, evaluation of the need for time/temperature control for safety could consider data from microbial growth models that are based on the interaction of only pH and a_w. Individual companies have shown that predictive pathogen

growth models for a particular food that incorporate preservative effects can be useful tools in reducing the need for extensive challenge testing and risk assessment.

The pathogens of concern and appropriate control processes that inactivate those pathogens differ for each category of foods. The panel listed such pathogens and control processes in Table 1 below.

Table 1. Pathogens of concern and control methods for various product categories.

Product Category (examples of possible foods for evaluation)	Pathogens of Concern	Types of Process Control[1] (alone and in Combination)
Meats and poultry (fermented sausage)	*Clostridium botulinum*[5] and *Clostridium perfringens, Salmonella* spp., enterohemmorrhagic *Escherichia coli, Camplylobacter jejuni, Yersinia enterocolitica, Staphylococcus aureus, Listeria monocytogenes*	Time/temperature, pH, a_w, preservatives, moisture protein ratio, fermentation, heat processing
Fish and seafood (smoked fish)	*Vibrio vulnificus, Vibrio parahaemolyticus, Vibrio cholerae, C. botulinum*[5], *L. monocytogenes, Salmonella* spp., *Shigella* spp., *S. aureus*	Time/temperature, harvest site control, fermentation, pH, a_w, water-phase salt, preservatives, drying, salting
Fruits and vegetables (peeled carrots)	*Salmonella* spp., *Shigella* spp., enterohemmorrhagic *E. coli*, *L. monocytogenes, Bacillus cereus, C. botulinum*[5], *Y. enterocolitica*	Production control (Good Agriculture Practices), time/temperature, cooking, preservation techniques
Cereal grains and related products (fresh pasta, foccacia)	*Salmonella* spp., *S. aureus, B. cereus, C. botulinum*[5]	Cooking, a_w, pH, preservatives, time/temperature
Fats, oils & salad dressings (garlic-in-oil)	*S. aureus*[2], *Salmonella* spp.[2], *B. cereus*[2], *C. botulinum*[2,]	pH, a_w, salt
Butter and margarine (light salted butter)	*S. aureus, L. monocytogenes, Y. enterocolitica*	Production/raw ingredient quality control, moisture droplet size in the water-in-oil emulsion, water phase salt, a_w
Sugars and syrups (light maple syrup)	*C. botulinum*[3,]	a_w, acidification (light syrups)
Eggs and egg products (merengue)	*Salmonella* spp.[4], *L. monocytogenes*[4]	Production control, cooking/pasteurization, time/temperature
Milk and milk products (yoghurt)	*Salmonella* spp.[4], *L. monocytogenes*[4], enterohemmorrhagic *E. coli*[4], *S. aureus*[4], *B. cereus* (cells[4] and spores[5]), *C. botulinum* (cells[4] and spores[5]), *Campylobacter jejuni*[4]	Production control, time/temperature, cooking/pasteurization, a_w, preservatives
Cheese and cheese products (Natural Swiss cheese)	*Salmonella* spp.[4], *L. monocytogenes*[4], enterohemmorrhagic *E. coli*[4], *S. aureus*[4], *Shigella* spp.[4], *C. botulinum* (cells[4] and spores[5])	Production control, moisture content, a_W, pasteurization, preservatives, pH
Combination products (cheese with veg. pieces, pumpkin pie, stuffed pastry)	Variable, based on raw materials and processing	Variable, based on raw materials and product

[1]Good Manufacturing Practices would help in reducing the hazards. For meats, poultry, and fish and seafood products the Hazard Analysis Critical Control Point principles should be implemented as a control system.

[2]A pH > 4.0 and a_w ~ 0.92 in salad dressings and mayonnaise would preclude the growth of pathogens of concern.
[3]Only a concern in light syrups and can be controlled by acidification.
[4]In pasteurized products, all pre-processing vegetative pathogens would be controlled.
[5]Only a concern in anoxic environments.

Effects of Processing Technologies. Establishment of traditional thermal processes (for example, canning, pasteurization, baking, and cooking) for foods has been based on two main factors: 1) knowledge of the thermal inactivation kinetics of the most heat-resistant pathogen of concern for each specific food product; and 2) determination of the nature of heat transfer properties of the food system. The validity of a thermal process must be confirmed by an inoculated challenge test conducted on the product under actual plant conditions using surrogate microorganisms as biological indicators to mimic pathogens. Thus, the two factors described above, which are well established for thermal processes, should be used for establishing and validating scheduled new thermal processes based on thermal effect on microorganisms, such as microwave heating.

For other preservation processes not based on heat inactivation, key pathogens of concern and nonpathogenic surrogates need to be identified and their significance evaluated.

NSF and American Bakers Association. Both the ABA and the NSF testing protocols suffer from significant weaknesses that hamper their usefulness in determining whether a food can be safely stored at room temperature. The NSF protocol takes an overly stringent approach, whereas the ABA protocol is sometimes overly permissive. Two major significant differences between the two protocols are 1) the consideration (or lack of consideration) of the process the food did or will undergo, and 2) the selection of organisms used or not used to inoculate the food. The panel developed a general protocol for microbiological challenge testing. Table 2 presents a comparison of the features of these protocols.

Table 2. Summary of comparison of NSF, ABA and expert panel protocols to determine if a food requires time /temperature control for safety.

Item	ABA	NSF	Panel's Alternative Protocol
Type of product	Pumpkin pie	Four groups: bread with vegetables and cheese pre-bake, filled post-bake, filled pre-bake, toppings. Traditional and other products excluded.	Any food product proposed to be stored outside temperature control.
Consideration of process	Yes (Good Manufacturing Practices, [GMP's], baking temperature, cooling, and packaging)	No	Yes. Additional information for validation of process also required.
Microorganisms tested	Aerobic Plate Counts (APC), *Staphylococcus aureus*, coliforms, salmonellae	*Bacillus cereus*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, Salmonella spp, *S. aureus*, *Clostridium perfringens* depending on pH and a_w	Organisms should be selected based on history of safety, formulation, storage atmosphere environment and packaging of the food.
Inoculation type	None (indigenous only)	Composite of 5 strains of each organism. Each composite inoculated into the product separately.	Composite of multiple strains of each organism. Each composite inoculated into the product separately.
Inoculation method	Not applicable	Prescribed in phosphate buffer.	Prepared in system that mimics the product: Previously mixed with buffer or water, directly added to product, aseptically injected, mixed powder product, or lyophilized, depending on the product
Inoculum preparation	Not applicable	Aerobes cultured in tryptic soy broth, *C. perfringens* cultured in fluid thioglycolate (sp?) broth	Cultures grown in suitable media under either optimal or food-adapted conditions. Spores are washed and heat-shocked before or after inoculation.
Inoculum position	Not applicable	Each unique component and each unique interface between components at both internal and external surfaces	Each component, and each unique interface between components, but only where the organisms of concern would survive the process or be reintroduced post-processing.
Inadvertent product modification	Not applicable	Addition of the inoculum in buffer has a potential to change product water activity.	Additional measurements of a_w should be taken to insure that inoculation technique does not influence product a_w.
Inoculum technique	Not applicable	No consideration for relative component weights given when splitting inoculum between components.	Not applicable

Sampling times	Two: within 24 h of packaging, and at end of shelf life	One to ten: depending on intended shelf life	A minimum of 5 times over shelf life, including zero time.
Pass criteria	No pathogens detected, APC less than 1,000 CFU after bake, and less than 100,000 CFU at end of shelf life	Less than 1 log CFU increase for any pathogen by the end of the study and not to exceed 1 log CFU for any pathogens at two consecutive time points before the end of the study.	Depending on the pathogen, less than 1 or 4 log increase at any point in shelf life for vegetative pathogen(s) of concern and no detectable toxin at the end of the shelf life for toxin-forming microbes.
Other tests	Oxidation/Reduction potential, pH, a_W	pH, a_W	pH, a_w, pH/aw interaction,
Process	Process is considered by use of natural inoculum.	Process is not considered, since pathogens are inoculated into the food after processing.	Process should be considered in the selection of appropriate microbes for use in the challenge study. Data to validate the process should be provided.
Methods	Association of Official Analytical Chemistry/Bacteriological Analytical Manual	Compendium of Methods for the Microbiological Examinations of Foods	Any reproducible, validated method is acceptable.
Duration of study	The study lasts until the use by date, which is calculated by multiplying 1.3 times the sell by date.	The study lasts 1.3 times the time the products will be out of temperature control.	The study should last for at least the shelf life of the product, but 1.3 times the intended shelf life is recommended.
Spoilage	Addressed indirectly with APC	Not applicable	Testing of inoculated sample for background bacteria
Replication	6 samples at beginning and 6 at end of one production run	3 lots, 2 samples/lots, over shelf life	Minimum of 3/sampling time unless this is a revalidation study or control sample (less samples are needed)
Anaerobes	Only an O/R potential measurement is made, no microbial tests are done.	*C. perfringens*	*C. botulinum* itself is used, with toxin production as the definitive measure of safety.
Microbial growth modeling	Not applicable	Not applicable	Properly validated growth models can be used alone or in combination with microbial challenge studies.
History of safe use	Not applicable	Not applicable	A long history of safe used can be considered in combination with appropriate scientific rationale instead of challenge studies.

Development of a Framework. Based on the criteria used by industry, government, and trade organizations; survey data collected by the panel; available scientific literature; and the panelists' experience on this subject, a framework was developed to facilitate the determination of whether or not a food needs time/temperature control for safety.

Following is a figure and description of the proposed framework to determine whether a food needs time/temperature control for safety. Before proceeding with Step 1 of the evaluation process, the evaluator needs to make a succinct review of the food product in question. If the food may already be held hot or cold for safety reasons, there is no need not proceed any further. Also, product history in combination with a valid scientific rationale that justifies such safe history of use may be used as criteria to designate a food as non-TCS food.

The panel concluded that the appropriate scientific evidence on pH, water activity, and pH/a_W interaction exists to allow for the evaluation of a food. Two pH/a_W tables were designed. If heat or process technologies alternative to heat are applied, then effectiveness needs validation. For some products, and specially combination products, the analysis of pH and a_W may be inaccurate. Consequently, for these products the pH and a_w would not be considered as controlling factors without supporting data.

If the determination indicates that a food may be a TCS in the table, an analysis may be performed to assess the microbial risk of holding the product at ambient temperature. A comprehensive description of the product as part of this analysis is compiled. If historical information regarding product safety is considered, it should be provided with a sound scientific rationale. In addition to the usual factors, time of expected storage and display might also be considered. If the duration of storage and/or display is less than that needed for microbial growth and/or toxin production, adequate control may be achieved through a variety of time and temperature combinations. Under certain circumstances, time alone at ambient temperatures can be used to control product safety. The USDA Pathogen Modeling Program v. 5.1 could be used, with appropriate interpretation, to assist in the determination of pathogen growth. Unless used conservatively, it is often more appropriate to use them in combination with challenge testing. In the absence of an appropriate and validated prediction model, a challenge test alone could be used. If the hazard analysis indicates the product is a non-TCS, the product can be stored at room temperature. If the product is identified as a TCS, the evaluator can either decide to modify the product, change the processing and handling it undergoes, control pathogen growth with time/temperature, or revisit the commercial feasibility of the product.

Framework for determining if time/temperature is required for safety

The food in question may already be held hot or cold for safety reasons. In this case, and if there is no desire for ambient temperature storage, an analysis using this framework is not needed. If the need to control the temperature of the product for safety reasons is unknown, a review of the food, its ingredients, and general methods of preparation should precede the evaluation of the food. If the food, as described, has a substantial and extensive history of safe use without time/temperature control, and there is enough scientific rationale that supports such safe history of use, then the food may continue to be classified as not requiring temperature control for safety, or non-TCS (see also Chapter 3, section 4.2.). If there is no known history of safe use, proceed with Step 1.

Step 1. Was the food treated to destroy vegetative cells of potential pathogens and packaged to avoid recontamination? If yes, position your product in Table A according to its pH and water activity (a_w). If not, position your product in Table B according to its pH and a_w.

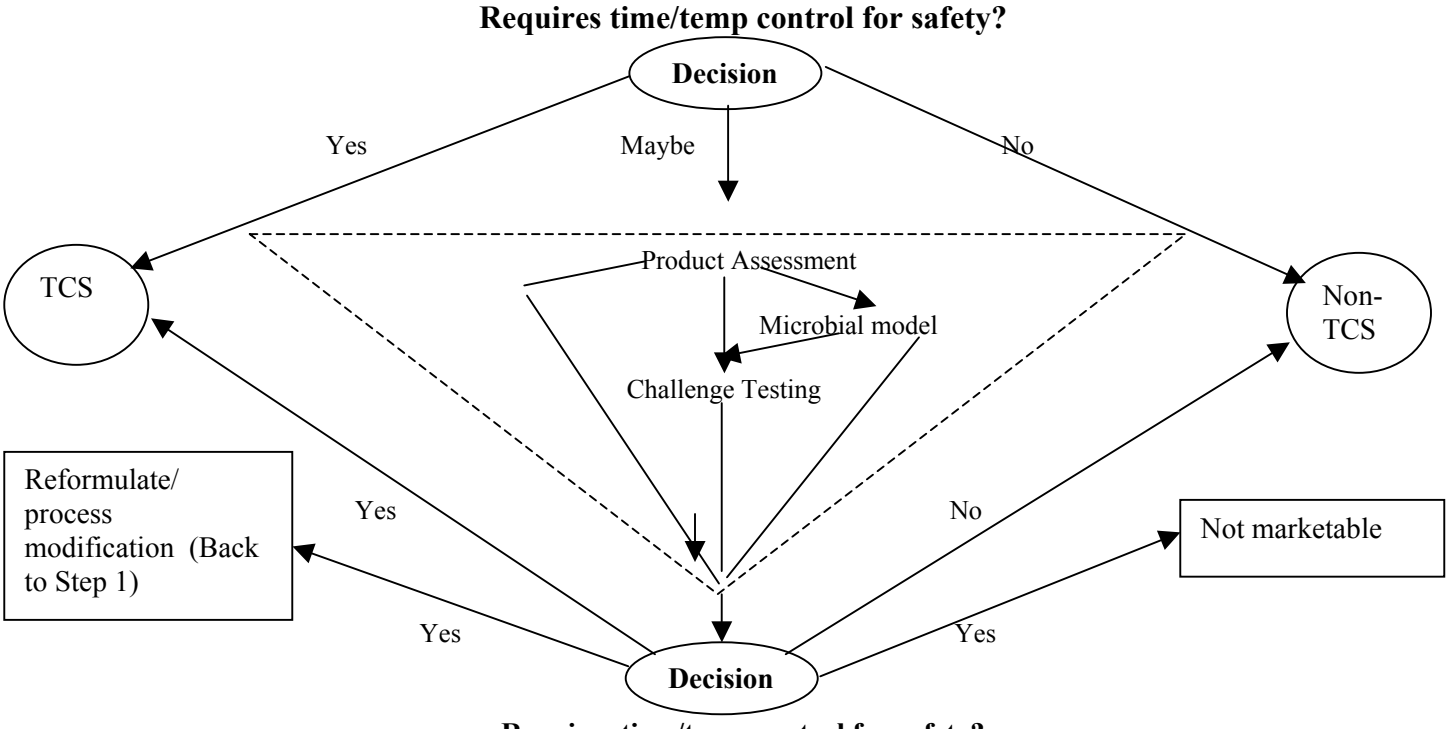
Table A. Control of spores: Product treated to control vegetative cells and protected from recontamination.

Critical a_w values	Critical pH values		
	4.6 or less	>4.6– 5.6	>5.6
0.92 or less	Non-TCS	Non-TCS	Non-TCS
>0.92–.95	Non-TCS	Non-TCS	?
>0.95	Non-TCS	?	?

Table B. Control of vegetative cells and spores: Product not treated or treated but not protected from recontamination.

Critical a_w values	Critical pH values			
	<4.2	4.2 – 4.6	>4.6– 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88– 0.90	Non-TCS	Non-TCS	Non-TCS	?
>0.90–.92	Non-TCS	Non-TCS	?	?
>0.92	Non-TCS	?	?	?

Step 2. If the food is classified as a non-TCS food according to Step 1 above, it may be stored and held safely without regard to time or temperature. If the need for time/temperature control is questionable, the food should be held either hot or cold for safety, or subjected to a product assessment as the next step in determining the appropriate classification.



The panel's framework on time/temperature control of foods for safety was critiqued by applying it to a variety of foods. Each step of the framework has been described as it applies to the food under consideration. Most of the data on the individual foods were from industry studies submitted to the panel.

In summary, the panel introduced a new approach for evaluating foods that may need time/temperature control for safety. This framework was based on scientific data from peer-reviewed publications that were further evaluated by the panel. The panel recognizes that the implementation of its 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.