Chapter 2

Current and Proposed Definitions of "Potentially Hazardous Foods"

1. Regulation review

The IFT panel searched domestic and international regulations and guidelines for terms similar to the FDA Food Code definition of "potentially hazardous foods" (PHF) and associated requirements with a focus on the scientific basis for these definitions. Australia and Canada, like the United States, use the term "potentially hazardous foods" in their food safety regulations (ANZFA 2001a, CFIS 2001ab, FDA 1999). 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 for temperature control to protect public health. Lists of products that need to be temperature controlled for safety are sometimes included. These products generally have a history of association with illness in the absence of temperature control. A summary of regulations used by agencies in the United States, Australia, Canada, the United Kingdom, and the European Union follows.

1.1 Food and Drug Administration

The following is the definition used in the FDA Food Code (FDA 1999, pt 1-201.10[B][61]):

> (a) "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:
>
> (i) The rapid and progressive growth of infectious or toxigenic microorganisms;
>
> (ii) The growth and toxin production of *Clostridium botulinum*; or
>
> (iii) In raw shell eggs, the growth of *Salmonella* Enteritidis.
>
> (b) "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.
>
> (c) "Potentially hazardous food" does not include:
>
> (i) An air-cooled hard-boiled egg with shell intact;
>
> (ii) A food with an a_W value of 0.85 or less;

(iii) A food with a pH level of 4.6 or below when measured at 24 °C (75 °F);

(iv) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution; and

(v) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S.* Enteritidis in eggs or *C. botulinum* can not occur, such as a food that has an a_W and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms.

(vi) A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

1.2. United States Department of Agriculture (USDA)

USDA/Food Safety and Inspection Service (FSIS) Food Standards and Labeling Policy Book (USDA 1996) identifies criteria for a "shelf-stable" product. Criteria include product specific Moisture Protein Ratio (MPR) such as: "dry sausage with Moisture Protein Ratio (MPR) ≤ 1.9:1, semi-dry sausage with MPR ≤ 3.1:1 with a pH ≤ 5.0, or be commercially sterilized . Alternatively, non-refrigerated, semi-dry shelf stable sausages are those that are fermented to a pH of 4.5 or lower (or 4.6 combined with a a_w of less than 0.91); are in an intact form or, if sliced, are vacuum packed; have an internal brine concentration of no less than 5%; are cured with nitrite; and are cured smoked with wood." With the full implementation of HACCP, 9 C.F.R. § 417.4 (2001), establishments are required to have records validating their critical limits to control hazards. The MPR criteria provide an alternative approach to pH and a_w alone that recognizes the effectiveness of combined multiple controls. A product processed in the retail environment and therefore not covered under the USDA/FSIS HACCP rule should meet these same requirements for shelf stability and have records documenting control of hazards.

1.3. State regulations

Most states have adopted the FDA Food Code definition of "potentially hazardous foods" or the previous FDA/AFDO Retail Code or FDA Food Service Code, which do not state a specific a_w or pH value, but use a general definition that has been interpreted by the FDA as including $a_w \leq 0.85$ and pH ≤4.6. The state of Washington, and a county within that state, King County Seattle, have adopted a modified requirement of pH ≤ 4.6 and $a_w \leq 0.90$ (Wash. Admin. Code § 246-215-010).

A possible explanation for the adoption of a higher a_w limit follows. Toxin production by *Staphylococcus aureus* under anaerobic conditions is limited by an a_W of 0.92. Under aerobic conditions, toxin production is generally inhibited at $a_W < 0.90$ (Baird-Parker 1990). However, studies in pure culture have demonstrated toxin production at $a_W = 0.88$ adjusted with glycol (Stewart and others 2001). Additional studies in food systems are necessary to validate the effectiveness of a_W 0.90 as an effective control.

1.4. International regulations

1.4.1. Australia

In July 2000, the Australia New Zealand Food Standards Council adopted three Food Safety Standards: Interpretation and Application (Standard 3.1.1), Food Safety Practices and General Requirements (Standard 3.2.2), and Food Premises and Equipment (Standard 3.2.3) into the Australia New Zealand Food Standards Code. These standards will replace existing State and Territory regulations. Standard 3.2.2 defines "potentially hazardous food" as "food that has to be kept at certain temperatures to minimize the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in food" (ANZFA 2001a). The regulations further define specific temperature requirements for a food business to receive, store, display, or transport a "potentially hazardous food" (for example, ≤ 5 °C [41 °F] or ≥ 60 °C [140 °F]). Alternatively, it requires that "the food business demonstrate that maintenance of the food at a temperature for the period of time for which it will be so maintained, will not adversely affect the microbiological safety of the food" (ANZFA 2001a). The standard also requires specific times and temperatures for cooling cooked "potentially hazardous foods".

Australia's Priority Classification System for Food Businesses" (ANZFA 2001b) provides further discussion of high, medium, and low risk foods as follows:

- High risk foods are foods that "may contain pathogenic microorganisms and will normally support formation of toxins or growth of pathogenic microorganisms." Examples are raw meat, fish, oysters, poultry, milk, tofu, fresh filed pasta, meat pies, frankfurts, salami, cooked rice, and lasagne.

- Medium-risk foods are foods that "may contain pathogenic microorganisms but will not normally support their growth due to food characteristics; or food that is unlikely to contain pathogenic microorganisms due to food type or processing but may support formation of toxins or growth of pathogenic microorganisms." Examples are fruits and vegetables, orange

juice, canned meats, pasteurised milk, dairy products, ice cream, peanut butter, and milk-based confectionery.

- Low-risk foods are foods that "are unlikely to contain pathogenic microorganisms and will not normally support their growth due to food characteristics." Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol, and fats and oils.

1.4.2. Canada

The Canadian Food Inspection Agency (CFIA) *Food Retail and Food Services Regulation* defines "potentially hazardous food" as "food in a form or state which is capable of supporting the growth of pathogenic microorganisms or the production of toxins" (CFIS 2001a). This definition which is similar to some of the provisions in the FDA Food Code is expanded in the CFIA Food Retail and Food Services Code as follows: "any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish (edible mollusca and crustacea), or any other ingredients, in a form capable of supporting growth of infectious and/or toxigenic microorganism. This does not include foods which have a pH of 4.6 or below and foods which have an a_W of 0.85 or less" (CFIS 2001b). The Canadian Code further interprets potentially hazardous foods in its Appendix A (CFIS 2001b), which extrapolates interpretative questions from the "Guidelines for Production, Distribution, Retailing and Use of Refrigerated Prepackaged Foods with Extended Shelf Life" (Health Canada, Health Protection Branch 1992 Mar 1; Guideline No. 7). The Canadian Code's a_W limit is based on control of *S. aureus* growth. As explained in Chapter 3, however, toxin is inhibited at a higher value even under optimum conditions. Conversely, lower pH values are required in some situations to control *Salmonella* spp. for an extended period of time.

1.4.3. United Kingdom

The United Kingdom does not use the term "potentially hazardous food" but identifies foods that require temperature control in the *Food Safety (Temperature Control) Regulations,* (1995) SI 1995/2200. These regulations require "Chill holding" at ≤8 °C (46 °F) for "any food…which is likely to support the growth of pathogenic micro-organisms or the formation of toxins." Foods considered likely to fall into this category include the following:

- Dairy products, such as soft or semi-hard cheeses ripened by molds and/or bacteria, and dairy based desserts, unless the pH is <4.5;
- Cooked products such as meat, fish, eggs, milk, hard and soft cheese, rice, pulses, and vegetables;

- Smoked or cured fish;
- Smoked or cured ready-to-eat meat which is not ambient shelf-stable;
- Prepared ready-to-eat foods such as prepared vegetables, salads;
- Uncooked or partly cooked pastry and dough products such as pizzas, sausage rolls, or fresh pasta.

Time-related exemptions from temperature control are provided for the following products:

- "(a) cooked pies and pasties containing meat, fish or any substitute for meat or fish or vegetables or cheese or any combination thereof encased in pastry into which nothing has been introduced after baking and sausage rolls which are intended to be sold on the day of their production or the next day;
- "(b) uncut baked egg and milk pastry product, e.g., custard tarts and Yorkshire curd tarts intended for sale within 24 hours of production."

General exemptions from chill holding requirements are given to "foods which, for the duration of their shelf life, may be kept at ambient temperatures with no risk to health." A food business must provide "well-founded scientific assessment of the safety of the food at the specified temperature and shelf-life" for products recommended to be held above 8 °C (46 °F). Regulations do not articulate data requirements, rather they stipulate that assessments should be done by a "competent laboratory," either in-house, for large businesses, or through independent laboratories.

These regulations recognize the influence of processing and time. For example, baking destroys vegetative cells and dehydrates exterior surfaces. The potential for growth of pathogenic spore formers exists, but time is used to control this hazard. The panel questions whether there is adequate scientific basis to support a time of one day of safety at ambient temperature for the time/related exemptions.

1.4.4. European Union

The European Union *Hygiene of Foodstuffs E(876)* specifies that "Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health" (The Council of the European Communities 1993). Specific times, temperatures, or other factors are not identified, therefore no parameters require justification.

2. Critique of FDA's "potentially hazardous foods" definition

The panel reviewed the current FDA Food Code definition for "potentially hazardous foods" (PHF) (see section 1.1) and the history of its development. The original concept, and that used elsewhere in the world, acknowledges that certain foods (for example, meat, poultry, milk products, eggs, and other high a_W, neutral products) require time/temperature control to maintain safety. These products have a well-documented history of causing foodborne illness outbreaks when subjected to temperature abuse; therefore, time/temperature control is essential to protect the public health. However, 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 science-based factors other than pH and a_w. It is the opinion of the panel that the current definition of PHF 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 "potentially hazardous foods" when, in fact, they are not.

The term "potentially hazardous food," in its current usage, causes considerable confusion. This definition (which limits or prescribes consideration of factors other than pH and a_W) is narrower than what the term implies in that temperature control alone cannot provide product safety. Many foods that meet the current definition can be hazardous if pathogens are present at infectious levels. For example, temperature control will not prevent outbreaks caused by *Escherichia coli* O157:H7 or *Salmonella* spp. in juices with pH of less than 4.6. Conversely, certain fermented sausages have pH and a_W levels higher than those in the definition, yet have a well-documented history and validation of safety at room temperature. In addition, the food safety community does not generally make use of the term PHF; other terms, such as high-risk food, are used.

The panel recommends use 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 panel also proposes the use of the term "temperature controlled for safety" (TCS) foods in place of

PHF. This term accurately describes both what is required −temperature control with time implied−and why it is required−safety. The TCS term avoids confusion with the term "hazard" as it is applied in HACCP. It also avoids the inclusion of foods that do not require time/temperature control for safety, and avoids confusion related to products that present a risk to consumers where the risk is not controlled by storage or holding temperature (for example, *E. coli* O157:H7 in fruit juice). The term "temperature controlled for safety" is a more accurate reflection of the true concept behind the current definition for PHF. The use of both terms, TCS and PHF, during the transition can facilitate migration from one term to the other. Other terms considered by the panel (and the rationales for their exclusion) follow:

- Temperature Sensitive Food or Temperature Controlled Food (the safety aspect is not explicit)

- Microbiologically Unstable Food (does not articulate safety concerns and does not identify the control strategy)

- Time/Temperature Sensitive Food (more cumbersome than the term proposed, does not articulate safety, and time can be included in a simplified definition)

- High-Risk Products (can be confused with risk assessment efforts and does not identify control strategy)

- Temperature Safe Food

- TempSafe Food

The agency might consider adopting a term for defining foods that require time/temperature control for safety such as "temperature controlled for safety" (TCS). The panel suggests using a definition for TCS foods such as "foods that require time/temperature control to limit pathogen growth or toxin formation that constitutes a threat to public health."

As part of the charge, the panel also reviewed the current Food Code definition 1-201.10 (B) (61) (see section 1.1. of this chapter) and has the following observations relative to the scientific basis for the definition:

Section a

The term "rapid and progressive" in Section a in the Food Code is no longer appropriate. The term was originally used at a time when shelf life of most foods was relatively short and the concern was growth of pathogens occurring in hours rather than days. Current production, processing and packaging technologies, extended shelf life products, distribution systems, and consumer-use practices have altered this paradigm. Therefore, microbial growth need not be rapid to present a threat to public health in some food products. Progressive growth of pathogens to levels that present a threat to public health or levels that produce toxin are the key issues. The amount of growth required to present a threat to public health is specific to the organism, the food, and other factors discussed subsequently in this report. Removing the subjective requirement for "rapid" growth removes the need to specifically address *Clostridium botulinum* in the definition. Formation of hazardous levels of any toxic substance through microbial growth is unacceptable. Specifics related to *C. botulinum* control and *Salmonella* Enteritidis in eggs may be more appropriately covered in the recommended interpretive guidelines.

Section b

The food items listed in Section b of the Food Code definition have been linked to foodborne illness. Time/temperature abuse has been a contributing factor for most of the products listed in this section.

Section c

The pH and a_W values in Section c are problematic. The actual values that restrict growth vary with different acidulants for pH, humectants for a_W, and other properties of the food under consideration. Technically, an a_W of 0.85 is inappropriately low as a general a_W minimum because most pathogens are inhibited at values well above 0.86 and *S. aureus* toxin formation (the true hazard) is restricted at higher a_W values (see Chapter 3). Conversely, a pH of 4.6 may not control the growth of certain pathogens with some acidulants within the intended "use time." There is no scientific basis to single out *C. botulinum* and *Salmonella* Enteritidis in this section. Control of all relevant pathogens must be addressed. The term "laboratory evidence" currently used in the Food Code definition is unnecessarily restrictive in describing potential documentation for demonstrating safe storage. Supporting documentation should be expanded to include validated modeling programs in addition to laboratory evidence. The use of the term "scientific evidence" should be modified to include laboratory, literature, and modeling evidence. Section c(vi) in the Food Code adds to confusion that is not necessary if the term PHF is replaced with the more descriptive term TCS. The concept of refrigeration is already captured under temperature control in the term "temperature controlled for safety," and therefore, no further explanation on storage temperature conditions for hermetically-sealed containers would be needed.

References

[ANZFA] Australian New Zealand Food Authority. 2001a. The Food Standards Code,Vol. 2, Standard 3.2.2; Food Safety Practices and General Requirements (Australia only). <http://www.anzfa.gov.au/foodstandards/foodstandardscodecontents/standard32.cfm>. Accessed 2001 Oct 9.

[ANZFA] Australian New Zealand Food Authority. 2001b. Food safety: the priority classification system for food business. Lkd. <http://www.anzfa.gov.au/mediareleasespublications/publications/index.cfm>. Accessed 2001 Nov 20.

Baird-Parker TC. 1990. The staphylococci--an introduction. J Appl Bacteriol Symposium Suppl:1S-8S. (cited in ICMSF 1996a).

[CFIS] Canadian Food Inspection System, Canadian Food Inspection System Implementation Group. 2001a. Food retail and food services regulation. Lkd. Canadian Food Inspection System Model Regulations and Codes web page at <http://www.cfis.agr.ca/english/regcode/frr_frme.htm>. Accessed 2001 Oct 10.

[CFIS] Canadian Food Inspection System, Canadian Food Inspection System Implementation Group. 2001b. Food retail and food services code. Lkd. Canadian Food Inspection System Model Regulations and Codes web page at <http://www.cfis.agr.ca/english/refcode/frfsc_frme.htm>. Accessed 2001 Oct. 10.

[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>.

[HC] Health Canada, Health Protection Branch. 1992 Mar 1. Guidelines for production, distribution, retailing and use of refrigerated prepackaged foods with extended shelf life [Guideline No. 7].

Stewart CM, Cole MB, Legan JD, Slade L, Vandeven MH, Schaffner DW. 2001. Modeling the growth boundary of *Staphylococcus aureus* for risk assessment purposes. J Food Prot 64(1):51-7.

The Council of the European Communities. 1993. Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. Official Journal L 175, 19/07/1993 p. 0001-0011. Annex Chapter IX, paragraph 4. <http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393L0043.html>. Accessed 2001 Nov 8.

[UK] United Kingdom, Ministry of Agriculture, Fisheries and Food. 1995. The Food Safety (Temperature Control) Regulations. London: HMSO.

[USDA] U.S. Dept. of Agriculture, Food Safety and Inspection Service. 1996 [with change 98-01 (Sept 1996 thru Feb 1998)]. Food standards and labeling policy book. Available from: Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954; (202)512-1800.