Chapter 8

Framework Developed to Determine Whether Foods Need Time/Temperature Control for Safety

1. Description of framework

The variety and novelty of the foods currently available to consumers has resulted in a complex situation when determining whether a food needs time/temperature control for safety. Although there are many foods that need time/temperature control for safety (TCS), other foods require specific evaluation in order to determine their status as TCS or non-TCS foods. To facilitate the decision as to whether a food needs time/temperature control for safety, the panel developed a framework based on: in-depth evaluation of criteria used by industry, government, and trade organizations; survey data collected by the panel (see Appendix B); available scientific literature; and the panelists' own experience on this subject. The framework provides a stepwise process that considers holding time and temperature, product description, pH and a_w interaction, product assessment, challenge testing, and mathematical models. Decisions as to whether or not a food should be designated as TCS can be made at various steps of the framework. Performing the initial steps requires only limited experience and/or minimum training, while subsequent steps require knowledge of the product's pH and a_w. More technical expertise is needed for the analysis step which is based on product assessment, challenge studies, and predictive modeling. If it is determined that the product needs (or may need) time/temperature control for safety, a number of alternatives are presented in the framework that might be considered. For example, a decision might be made that a challenge study is so costly that the best alternative is to reformulate the product or control the time or temperature.

The following is a description of the proposed framework that the panel has developed to determine whether a food needs time/temperature control for safety (see section 2 of this chapter).

Before proceeding with Step 1 of the evaluation process, the evaluator needs to make a succinct review of the food product in question, including intrinsic and extrinsic factors that may affect microbial growth and potential hazards. (Detailed descriptions of factors and potential hazards that will help with this review are presented in Chapters 3 and 4.) The food may already be held hot or cold for safety reasons. In this case, and if there is no desire to store the food at ambient temperature, the trained decision-maker need not proceed any further. Product history, in combination with a robust scientific rationale that justifies such safe history of use, may also be used as criteria to designate a food as a non-TCS food not requiring further evaluation (see also Chapter 3, section 4.2.).

Step 1. The panel concluded that the appropriate scientific evidence exists to allow for the evaluation of a food according to its pH, water activity, and pH/a_W interaction. The panel also agreed that a product that is processed to eliminate vegetative cells needs to be addressed differently than an unprocessed product that received no treatment or a less robust treatment. The concern of possible post-process contamination also needs to be addressed. If a food is processed to inactivate bacteria and packaged so that there is no post-process contamination, the tolerable range conditions of a_W and pH are more permissive, since spores would become the only microbial hazard. For these reasons, the panel designed two pH/a_W tables: one for the control of spores (Table A), and one for the control of spores and vegetative cells (Table B). The rationale for the ranges of pH and a_W in determining whether a food is non-TCS versus TCS is based on minimum pH and a_W requirements for the pathogens of concern; that is, *Bacillus cereus* and *Clostridium botulinum* toxin production when controlling spores, and *Listeria monocytogenes*, *Staphylococcus aureus, Salmonella* spp*, C. botulinum*, and *B. cereus* when controlling both vegetative cells and spores (see Chapter 3, sections 2.1. and 2.2. and Appendix C). If process technologies other than heat are applied, then the effectiveness of the process needs to be validated. For this decision, the evaluator needs to have an understanding of both the process and the validation of its effectiveness in reducing pathogens of concern. It should be noted that for some products, the analysis of pH and a_W may be inaccurate, especially in the case of combination products (see Chapter 4, section 10). Consequently, for these products the pH and a_w would not be considered as controlling factors without supporting data from challenge studies.

Step 2. After the product's assignment to a box inside one of the tables, if the product is designated as non-TCS, it may be safely stored at room temperature. If the product is placed in a box indicating with a question mark (?) that it may require temperature control for safety, an analysis may be performed to assess the microbial risk of holding the product at ambient temperature. The evaluator may also decide not to perform the analysis, in which case the time and temperature of the product should be controlled for safety.

Product assessment. A comprehensive description of the product is the first task in this product assessment. This entails a detailed description of such factors as 1) potential pathogens, 2) intrinsic factors (for example, preservatives, antimicrobials, humectants, acidulants, and nutrients), 3) extrinsic factors (for example, packaging, atmosphere (MAP), use/shelf life, and temperature range of storage and use), 4) effectiveness of the processing for control of pathogens, and 5) possible post-process recontamination opportunities that may be present. If any of the factors precludes the growth of pathogens (for example, acetic acid as an acidulant at a reasonably low pH), the product may be designated non-TCS. Historical information regarding product safety should be considered by determining whether the food in question, or any of its ingredients, has been previously implicated as a common vehicle of foodborne disease after temperature abuse. Of particular importance are the microbiological agents that are responsible for illnesses associated with the food and the reported contributing factors that have led to documented illnesses. Has adequate temperature control been clearly documented as a factor that can prevent or reduce the risk of illness associated with the food? Lastly, 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 scientific basis for such safe use could be rationalized. As intrinsic or extrinsic factors change (for example, MAP or greatly extended shelf life), historical evidence alone is not appropriate in determining potential risk. Therefore, for a product to be identified as non-TCS based on history, the intrinsic and extrinsic factors affecting microbial growth need to have remained constant, and a scientific rationale needs to have been provided for the product's safe use (see also Chapter 3, section 4.2.).

Microbial growth models and challenge studies. In addition to the usual considerations, time of expected storage and display might also play a significant role in determining the classification of the food. Foods that have combinations of pH, a_w, preservatives, or other factors that are restrictive (but not prohibitive) to microbial growth and/or toxin production may not require refrigeration to protect public health. For example, 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. These factors can be considered in light of the product assessment and the microbial hazards of concern. The following is an example of how storage or holding time alone at ambient temperatures could be used to control product safety. If the microbiological concern for a specific food is the growth of *S. aureus*, the USDA Pathogen Modeling Program v. 5.1 could be used to estimate the time of storage where pathogen growth could occur. Using Table 8-1 with data generated from the model, a product with an a_w = 0.88 and pH = 5.5 could be safely stored at ambient temperature for weeks, assuming *S. aureus* would be the only microbial concern.

Table 8-1. Time estimates required for 3-log growth of *Staphylococcus aureus* at various pH and water activities (a_w) based on the USDA Pathogen Modeling Program v. 5.1

	PH			
a_w	**6.0**	**5.5**	**5.0**	**4.6**
0.94	Hours	Hours	Hours	Hours
0.92	Hours	Hours	Days	Days
0.90	Hours	Days	Days	Weeks
0.88	Days	Weeks	Months	Months
0.86	Weeks	Months	Months	Months

Days = 2–13 days
Weeks = 13–60 days
Months = >60 days

It must be emphasized, however, that general growth models such as the USDA Pathogen Modeling Program must be restricted in use because of limitations of the model parameters, microorganisms of concern, or other factors. Consequently, unless used conservatively, it is often more appropriate to use them in combination with challenge testing. Nevertheless, a general model can assist, for example, in selecting pathogens of concern for a challenge test. In the absence of an appropriate model, a challenge test alone could be used to determine whether pathogens of concern could grow under specified storage conditions (see Chapter 6 for guidelines on challenge testing). On the other hand, if an in-house model has been developed and validated for a particular food, it could be used to make such an assessment by itself or with challenge testing. At this point, a final decision needs to be made about the product's need to be time/temperature controlled. If the hazard analysis indicates that the product should be designated as non-TCS, the product can be stored at room temperature. If, on the contrary, the product is identified as 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.

2. 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.

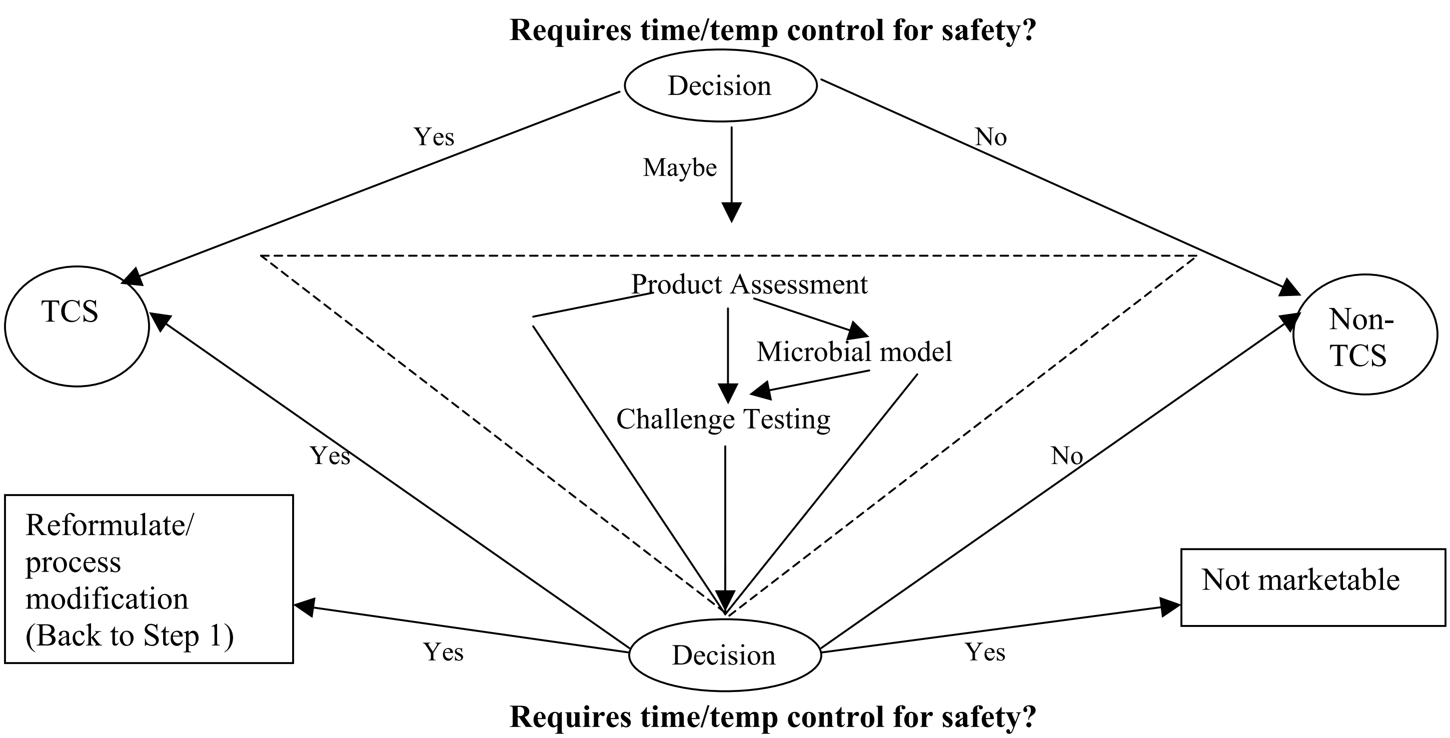
Table A. Control of spores: Product treated to control vegetative cells and protected from recontamination.

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.



3. Critique of framework. Application of framework to foods.

The panel's framework on time/temperature control of foods for safety was applied to the following foods as examples. Each step of the framework has been described as it applies to the food under consideration. Most of the data presented were from industry studies submitted to the panel in response to a survey of industry practices to determine whether a food needs time/temperature (see Appendix B).

3.1. Salad dressings

Product: Viscous, non-particulate[1] pourable salad dressing.

The product is not held hot or cold. The ingredients of the product are eggs, soybean oil, buttermilk, tomato paste, onion, garlic, spices, lemon juice, vinegar (2.5 – 5.4% salt), and potassium sorbate. Microbial hazards: *Clostridium botulinum*. The product is intended to be distributed and stored at ambient temperature for 7-9 mo. New product, so there is no history of use.

Step 1. Processing: Cold blended and filled in plastic or glass bottle. No heat applied.

Go to Table B.

Table: pH maximum of 4.2 and "high" (not specified) a_w.

Step 2. Decision: Product may be a temperature controlled for safety (TCS) food.

Product Assessment: Salad dressing is acidified with acetic acid. No microbiological hazard at pH 4.2.

Decision: Product is a Non-TCS.

[1]If salad dressing had particulate matter, then this product would need to be reevaluated.

3.2. Condiments: Mustard

Product: Viscous, non-particulate[1] mustard.

The product is not held hot or cold. The ingredients of the product are mustard seeds and vinegar (acetic acid). The product is intended to be distributed and stored at ambient temperature for extended shelf life. Microbial hazards: *Listeria monocytogenes, Salmonella* spp.*, Escherichia coli* O157:H7, *C. botulinum.* There is history of safe use without time/temperature control[2].

Step 1. Processing: Ground and blended. Go to Table B.

Table: pH maximum of 4.0 and "high" (not specified) a_w.

Decision: Product is a Non-TCS.

[1] If mustard had particulate matter, then this product needs to be reevaluated.
[2] If pH of mustard was above 4.2 or if acidulant was not acetic acid, then this product would need to be reevaluated.

3.3. Butter

Example 1

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature control of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.41 and a_W 0.897.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Product characteristics prevent *L. monocytogenes* growth. Predictive model (p 8-3) suggests that holding the product for hours at ambient temperature is safe.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_W, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 2

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature control of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.25 and a_W 0.897.

Step 2. Decision: Product is a Non-TCS food.

Example 3

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazard: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature control of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.94 and a_W 0.847.

Step 2. Decision: Product is a Non-TCS food.

Example 4

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream, lactic acid bacteria, and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature control of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.78 and a_W 0.863.

Step 2. Decision: Product is a Non-TCS.

Example 5

Product: Unsalted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.91 and a_W 0.921.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_W, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 6

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.98 and a_W 0.941.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_W, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 7

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned. Go to Table B.

Table: pH 5.42 and a_W 0.907.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease $a_{W,}$ refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 8

Product: Salted light whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream, salt, water, tapioca, modified food starch, beta carotene, vitamin A, natural flavoring, lactic acid, vegetable mono and diglycerides, potasium sorbate, sodium benzoate. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.48 and a_W 0.985.

Step 2. Product may be a TCS food.

Product Assessment: Sodium benzoate and potassium sorbate may prevent pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease $a_{W,}$ refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 9

Product: Salted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.14 and a_W 0.822.

Step 2. Decision: Product is a Non-TCS food.

3.4. Margarine

Product: Margarine. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are soybean oil (80%), water and milk protein (19%), salt (0.9%), and potassium sorbate (.1%). The product is intended to be distributed and stored at ambient temperature for 3 mo. Microbiological hazards: *S. aureus, L. monocytogenes*. There is history of safe use without time/temperature control.

Step 1. Processing: Emulsification of oil blend/water preservative mixture. No heat applied. Go to Table B.

Table: pH 4.8 and a_W unknown.

Step 2. Product may be a TCS food.

Product Assessment: Sorbic acid in formulation prevents pathogen growth. Historically product is safe and stable.

Decision: Product is a Non-TCS.

3.5. Garlic-in-oil[1]

Product: Garlic-in-oil. The product is not held hot or cold. The ingredients of the product are chopped fresh garlic and oil. The product is intended to be distributed and stored at ambient temperature for extended shelf life. Outbreaks have been associated with *C. botulinum* toxin in garlic-in-oil.

Microbiological hazards: *C. botulinum* toxin production.

Step 1. Processing: Oil poured into chopped garlic in a bottle. Although no heat is applied, vegetative pathogens are not associated with this food. Go to Table A.

Table: pH> 4.6 and high a_W (not specified).

Step 2. Decision: Product may be a TCS food.

Product Assessment: No identified product characteristic that prevents spore-forming pathogen growth. Antimicrobial properties of garlic will prevent the growth of vegetative pathogens.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic or phosphoric acid to < 4.6, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

[1]Flavored oil will present negligible hazard due to lack of *C. botulinum* survival or growth in 100% oil.

3.6. Cheeses

Example 1

Product: Cream cheese. The product is not held hot or cold during use. The ingredients of the product are milk, cream, salt, gums. The product is intended to be distributed and stored at $\leq$ 7 °C (45 °F) for a maximum of 120 d. When in use, the tempered unopened product can be kept up to 48 h at ambient temperature. There is no history of botulism associated with cream-cheese products. Microbiological hazard: *C. botulinum.*

Step 1. Processing: Full fat, plain cream cheese, bulk packed and hot-filled > 68 °C (155 °F) in 3 lb/30 lb/ 50 lb tubs/blocks. Ready-to-eat after opening or baked. Go to Table A

Table: pH 4.7 to 5.1, a_W>0.97.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid to < 4.6, keep refrigerated--that is, eliminate tempering at ambient (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separate products were inoculated with 100 – 500 spores/g of either proteolytic A & B or non-proteolytic B cocktails of *C. botulinum* and held at 30 °C (86 °F) for 10 d. No toxin was detected throughout the study. Conclusion is that the unopened product can be stored safely at ambient temperature for up to 7 d based on a safety factor of 1.3 times shelf life of the product. However, loss of product quality dictates storage at ambient temperature for no longer than 48 h. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 2

Product: Process cheese sauce packed in 40 lb bag-in-box containers. The product is not held hot or cold during use. The ingredients of the product are cheddar cheese, milk, whey, milk fat, water, salt, sodium phosphate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 9 mo. The tempered unopened product can be kept 24 h at ambient temperature in foodservice establishments prior to use. New product, so there is no history of use. Microbiological hazards: C. *botulinum.*

Step 1. Processing: Heated to 85 °C (185 °F) for 1-2 min and hot-filled at 68-69 °C (155-165 °F) into bag-in-box containers. Ready-to-eat or heated prior to consumption. Go to Table A.

Table: pH 5.7 (target) and aw >0.95.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly certain ingredients such as sodium phosphate and sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Run formulation through a validated microbial model.

Predictive microbial modeling: Microbial model showed that the product would support the growth and toxigenesis of *C. botulinum.* A decision was made to reformulate by optimizing the controlling factors and their interactions. In this case, sorbic acid levels were adjusted from 0.08 % to 0.15 %. The reformulated product was run through the microbial model which gave a prediction of safety. Conclusion is that the reformulated unopened product may be tempered at room temperature for 24 h maximum. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 3

Product: Pasteurized process cheese slices, bulk packaged. The product is not held hot or cold during use. The ingredients of the product are milk, whey, cheese, milk fat, water, salt, sodium citrate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 8 mo. The tempered 96-slice pack can be kept for an 8 h shift at ambient temperature prior to use near to the grill in foodservice establishments to facilitate peeling of slices and melting on sandwiches. No history of pathogenic growth associated with commercial pasteurized process cheese slices. Product is subject to recontamination after opening. Microbial hazards: *L. monocytogenes, S. aureus, Salmonella* spp*., E. coli* O157:H7, *C. botulinum* (product does not receive a proteolytic botulinal cook).

Step 1. Processing: Heated to ≥ 66 °C (150 °F) for ≥ 30 s and cooled over a chill roll. Slices are then bulk packed in units of 96 slices. Ready-to-eat directly out of package or used in melt applications. Go to Table B.

Table: pH 5.7-5.8 and a_W >0.92.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Product was inoculated with 10^3 CFU/g *L. monocytogenes, S. aureus, E. coli* O157:H7, *Salmonella* spp*,* and *C. botulinum* (proteolytic strains only). Cocktails of each challenge organism were inoculated into separate samples. Inoculated product was incubated at 30°C (86°F) for 96 h. Results showed that *Salmonella* spp*, E. coli* O157:H7, and *L. monocytogenes* decreased in populations over the challenge period. *Staphylococcus aureus* levels remained constant during the challenge period, but were below levels that supported detectable enterotoxin production. No botulinal toxin was detected over the challenge period. From a safety perspective the opened product could be stored for 67 h at room temperature, based on a safety factor of 1.3 times shelf life of the product. Loss of product quality dictates that slices be tempered for no longer than 8 h.

Example 4

Product: Cheese blend for pizza topping. The product is not held hot or cold during use. The ingredients of the product are cheese, sodium chloride 1.81%, nitrite level <1ppm. The product is intended to be stored at ambient temperature for a maximum of 10 h before being baked. This is a new intended use, so there is no history of safe use. The microbiological hazards are the heat-stable toxins of *S.aureus* and *B. cereus.*

Step 1. Processing: Baked, but heat-stable toxins may remain. Go to Table B.

Table: pH 5.56 and a_W 0.978.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: 1,000 CFU/g of product inoculated with *S. aureus* and *B. cereus* and incubated at 27 °C (80 °F) for various lengths of time: No toxin was detected at 10 h. Product can be stored safely at room temperature for 7 h, based on a safety factor of 1.3 shelf life of the product.

Example 5

Description: Cheese-filled bread. The product is not held hot or cold during use. The ingredients of the product are process cheese, pastry covering, salt, glycerol. The product is intended to be distributed and stored at 4.4-7.3 °C (40-45 °F) for a maximum of 90 d, and then stored at ambient temperature for sale. New product, so there is no history of use. Microbiological hazard: *Bacillus cereus* and *Clostridium botulinum* toxin production.

Step 1. Processing: Baked to internal temperature of 88 °C (190 °F) and MAP packed with 100% N_2,. Go to Table B.

Table: pH 5.6-5.7 and a_W 0.93.

Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separated inocula of 500 spores of *C. botulinum* and 500 spores of *B. cereus* incubated at 13, 18.5, 30 °C (55, 65, 86 °F) for various lengths of time. No toxin production or *B.*

cereus growth at 30°C (86 °F) for 14 d. Product can be stored safely at room temperature for at least 10 d, based on a safety factor of 1.3 times shelf life of the product.

Example 6

Product : Monterey cheese slices. The product is not held hot or cold during use. The ingredients of the product are Monterey Jack cheese, milk fat, water, citrate and phosphate emulsifiers, salt (1.9-2.5%), sorbic acid (2000 ppm max), color. The product is intended to be distributed and stored refrigerated for 180-210 d, but used at room temperature in food service. New product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp., *E. coli* O157:H7.

Step 1. Processing: 71 °C (160 °F) for 30 s, hot filled, and sliced, but recontamination is possible. Go to Table B.

Table: pH 5.7-6.0, and a_W 0.94-0.95.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Sorbic acid as a preservative may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Inoculum with 1,000 CFU/g of *L. monocytogenes, S. aureus, Salmonella* spp., *E. coli* O157:H7 incubated at 30 °C (86 °F) for various lengths of time: No growth of any pathogen tested at 24 h, no *S. aureus* toxin, *E. coli*, *L. monocytogenes* and *Salmonella* spp was detected at 48 h. Although *E. coli*, *L. monocytogenes* and *Salmonella* spp. levels remain the same up to 72 h, *S. aureus* toxin was detected at 72 h. Product can be stored safely at room temperature for no more than 33 h, based on a safety factor of 1.3 times shelf life of the product.

3.7. Filled bakery product

Product: Cream-filled éclairs. The product is not held hot or cold during use. The ingredients of the product are pastry shell (water, eggs, flour, hydrogenated vegetable oil, baking powder, sodium acid pyrophosphate, baking soda, corn starch, monocalcium phosphate, salt, malted barley); filling (water, sugar, modified corn starch, dextrose, vegetable oil, cottonseed, mono and diglycerides, salt, carrageenan, glucono delta lactone, sodium benzoate and potassium sorbate (0.02%), polysorbate 60, soy lecithin, natural and artificial flavors colored w/Yellow). The product is intended to be distributed at ≤ 0 °C (32 °F) or refrigerated for a maximum of 180 d or 3 d, respectively, and stored at room temperature for a maximum of 4 h. This is a new product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp.

Step 1. Processing: Filling 88 °C (190 °F), cooled to 5 °C (41°F) in 4 h; shell >93 °C (200 °F), cooled to ambient but recontamination is possible. Go to Table B.

Table: pH 7.2 (shell), 5.1-5.8 (filling), a_W 0.87 (shell), 0.96-0.98 (filling).

Step 2. Decision: Product may be a TCS food.

Product Assessment: Benzoate, sorbate, and glucono delta lactone as preservatives may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Filling inoculated (and placed in shell) with 100-1,000 CFU/g with *L. monocytogenes, S. aureus, Salmonella* spp. incubated at 7, 12 and 26 °C (44.6, 53.6 and 78.8 °F) for various lengths of time. There was pathogen growth at 1 d. Product as processed and formulated cannot be stored safely at room temperature.

3.8. Breads

Example 1

Product: Pepper focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, roasted sliced red peppers, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp, and *C. botulinum*.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH (pepper and bread) 3.9-4.1[1] and a_W 0.99.

Step 2. Decision: Product is a non-TCS food.

[1]If only the bread or the peppers have low pH, then a challenge study should be performed

Example 2

Product: Plain focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH 5.5-5.3, and a_W 0.95-0.97.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth. Although product has properties similar to white bread, with a long history of safe use, some ingredients would not be in the formulation of white bread; therefore, the product may be a TCS food and should be further analyzed.
Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.