TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DIVISION FOR REGULATORY SERVICES
ENVIRONMENTAL AND CONSUMER SAFETY SECTION
POLICY, STANDARDS, AND QUALITY ASSURANCE UNIT
FOOD ESTABLISHMENTS GROUP

HOW TO DETERMINE IF A FOOD IS A PHF/TCS FOOD

Using pH, a_w, or the Interaction of pH and a_w to Determine If a Food Requires Time/Temperature Control for Safety (TCS)

INTRODUCTION

The 2006 Texas Food Establishment Rules definition and the 2005 Food and Drug Administration (FDA) Food Code definition of potentially hazardous food (PHF) were revised in several ways: to reflect a more accurate term for this type of food, to consider the control of all foodborne pathogens and to allow for the hurdle effect of pH and a_w interaction in determining whether time/temperature control for safety is required for any food. Criteria are provided in the definition to determine when a food does or does not require time/temperature control for safety. The Texas Food Establishment Rules, Section 229.164(o)(9), Time as a Public Health Control, also provides safety parameters to use when time alone (without temperature control) can be used.

In 2004, a Conference for Food Protection (CFP) committee was formed to work with the United States Food and Drug Administration on all of the issues that need to be clarified or developed to implement the changes in the 2005 Food Code relative to the definition of potentially hazardous food (PHF), which is now known as time/temperature control for safety food (TCS Food). The CFP's TCS Food Implementation Committee produced the TCS Guidance Document. The Texas Department of State Health Services has adopted the guidance document as a tool to determine whether or not a food is PHF/TCS. Some minor changes have been made in order to incorporate the language and requirements of the Texas Food Establishment Rules. Some of the language of the draft PHF Revised Decision Tree and Instructions document has been retained for clarity and continuity.

Specific items that need to be developed before successful implementation is possible include the following:

- A guide for retail or food service establishments, processing firms, or regulatory agencies that explains how and when to use Interaction Tables A and B in determining whether a food requires time/temperature control for safety (TCS).

- A guide on the design and/or assessment of challenge studies that may be used in cases when a food establishment or processing firm wishes to store a certain food at ambient temperature but is unable to do so based on the food's pH, water activity, or interaction of the two. This guide should address any policy changes that may have taken place because of the recommendations in the Institute of Food Technologists (IFT) Report, available at http://www.cfsan.fda.gov/~comm/ift4-toc.html.

- Design of a challenge study is critical to achieve valid results. Many important factors must be considered. Guidance for the design of challenge studies/product assessment is available in Chapter 6 and 7 of the IFT Report. Protocols developed by the American Bakers Association and NSF International are attached as Appendix D and E, respectively, in the IFT Report.

Potentially hazardous food (PHF)/TCS food is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The definition does not address foods that do not support growth but may contain an infectious or toxigenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether it is slow or rapid.

The definition of PHF/TCS food takes into consideration pH, a_w, pH and a_w interaction, heat treatment and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no or inadequate heat treatment. In addition, if the food is packaged after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazards of concern. In some foods, it is possible that neither the pH value nor the a_w value is low enough alone to control or eliminate pathogen growth; however, the interaction of pH and a_w may. This is an example of hurdle technology. Hurdle technology is utilized when several inhibitory factors are used together to control or eliminate pathogen growth that would otherwise be ineffective when used alone.

Another important factor to consider is combination products. A combination product is one in which there are two or more distinct food components and an interface between the two components which may have a different property than either of the components alone. Determine whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, fettuccine alfredo with chicken, or does it have a uniform consistency such as gravies, puddings or sauces? In these products, the pH at the interphase is important in determining if the item is a PHF/TCS food.

A well designed inoculation study such as those found in the IFT Report, the NSF International Standard #75, or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (irradiation, high pressure processing, pulsed light, ozonation, etc);
- combination products are prepared; or
- other extrinsic factors (packaging/atmospheres) or intrinsic factors (redox potential, salt content, etc.) found in the food are used to control or eliminate pathogen growth.

Before using Tables A and B in the Texas Food Establishment Rules, Section 229.162(74), of the definition of “potentially hazardous food/food requiring temperature control for safety (TCS)” in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is there intent to hold the food without using time or temperature control?

    - If the answer is "No", no further action is required. The decision tree is not needed to determine if the item is a PHF/TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in the Texas Food Establishment Rules, Section 229.162(74)?
- Does a product history with good scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as Ultra Heat-Treated (UHT) creamers, shelf-stable canned goods, etc.?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.cfsan.fda.gov/~comm/ift4-toc.html.

HOW TO DETERMINE WHETHER FOODS REQUIRE TIME/TEMPERATURE CONTROL FOR SAFETY (TCS)

A determination of whether a food requires TCS can be made at various steps in the evaluation process. Initial steps in the assessment require limited experience and training, while subsequent steps require technical expertise, a good knowledge of food microbiology, results from laboratory testing for pH and a_w, challenge studies, mathematical predictive modeling, or a combination of these. Results at various steps along the way help determine whether the product should be reformulated to be a non-PHF/non-TCS Food or held under temperature control for safety.

INTERACTION TABLES

Two Interaction Tables were added to the 2006 Texas Food Establishment Rules and to the 2005 FDA Food Code that use the values of pH and water activity in a food to determine if the food is a non-PHF/non-TCS Food because of its pH or water activity alone or due to the interaction of the two factors. When the pH and a_w combination does not result in the classification of the food as non-PHF/non-TCS Food, further product assessment (PA) is required. In the meantime, the food must be treated as PHF/TCS and held under time/temperature control.

The use of pH and water activity values in combination to determine the growth of microorganisms is known as the hurdle effect, a term applied by Leistner. This concept involves the use of several inhibitory factors, or hurdles, to inhibit pathogen growth, which when used alone would be ineffective.

The effects of pH, water activity, and the interaction of the two on the growth and toxin production of pathogens were determined by published articles and IFT members' proprietary information. Examples of the type of information used to generate these tables are included in Appendix B of the IFT Report, "Definition and Evaluation of Potentially Hazardous Foods" at http://www.cfsan.fda.gov/~comm/ift4-toc.html. Refer also to "Factors Affecting the Growth of Some Foodborne Pathogens" in FDA's Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (Bad Bug Book) at http://www.cfsan.fda.gov/~mow/factors.html.

DISCUSSION OF TABLE A

Table A, TFER §229.162 (74)

Figure: 25 TAC §229.162(74)(D)(i)

Table A. Control of spores: Product heat-treated to destroy vegetative cells and subsequently packaged.			
Critical a_w values	Critical pH values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	non-PHF/non-TCS	non-PHF/non-TCS	non-PHF/non-TCS
> 0.92 - .95	non-PHF/non-TCS	non-PHF/non-TCS	PHF/TCS
> 0.95	Non-PHF/non-TCS	PHF/TCS	PHF/TCS

PHF/TCS means further product assessment is necessary to determine if the food is non-PHF/non-TCS.

Table A considers the "Interaction of pH and water activity for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged." Use this table to determine if a food that is heat-treated and packaged is PHF/TCS Food or Non-PHF/Non-TCS Food, or whether further Product Assessment is required. Some considerations when using this table include:

- There can be no variations in the day-to-day preparation of the food in question with respect to maximum a_w or pH.
- To eliminate vegetative pathogens, the food must be cooked for the required time and temperature specified in TFER, Section 229.164(k) (no partial cooks).
- Care must be taken to ensure that no contamination occurs between heat treatment and packaging. That could include limiting the time before packaging (perhaps allowing only enough time to cool after heat treatment to prevent condensation inside the package) and having a dedicated work area that limits the potential for cross-contamination from condensation, equipment, and employees. Each heat treatment and packaging process must be judged on a case-by-case basis.
- With all vegetative pathogens destroyed and the food packaged to prevent recontamination, spore-forming pathogens, including Clostridium botulinum, Clostridium perfringens and Bacillus cereus, are the only remaining biological hazards of concern.
- Therefore, higher pH and a_w values than those reflected in Table B can be safely tolerated.

The limiting pH value to inhibit growth and toxin production of proteolytic Clostridium botulinum types A and B is 4.7; therefore, any heat-treated, packaged food with a pH ≤ 4.6 is considered non-PHF/non-TCS Food regardless of its water activity (see column under pH 4.6 or less – all non-PHF/non-TCS Food.

The lowest water activity value that allows growth and/or toxin production of Clostridium botulinum types A and B, Bacillus cereus, and Clostridium perfringens is 0.93; therefore, any heat-treated, packaged food with an a_w = 0.92 or less is considered non-PHF/non-TCS Food regardless of its pH.

DISCUSSION OF TABLE B

Table B, TFER §229.162 (74)

Figure: 25 TAC §229.162(74)(D)(ii)

Table B. Control of vegetative cells and spores: Product not heat-treated or heat-treated but not packaged.				
Critical a_w values	Critical pH values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	non-PHF/non-TCS	non-PHF/non-TCS	non-PHF/non-TCS	non-PHF/non-TCS
0.88 – 0.90	non-PHF/non-TCS	non-PHF/non-TCS	non-PHF/non-TCS	PHF/TCS
> 0.90 – 0.92	non-PHF/non-TCS	non-PHF/non-TCS	PHF/TCS	PHF/TCS
> 0.92	non-PHF/non-TCS	PHF/TCS	PHF/TCS	PHF/TCS

PHF/TCS means further product assessment is necessary to determine if the food is non-PHF/non-TCS.

Table B considers the "Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged." Use this table to determine if a food that is not heat-treated or that is heat-treated but not packaged is PHF/TCS Food or Non-PHF/Non-TCS Food, or whether further Product Assessment is required.

When dealing with a food that has not been heat-treated or that has been heat-treated but not packaged to prevent recontamination, considerations must be made for limiting the growth of both vegetative and spore-forming pathogens. Therefore, the table must consider the controlling or limiting pH and/or water activity for both.

The lowest pH value for Staphylococcus aureus growth is pH 4.2. This value is close to pH 4.4 for Listeria monocytogenes. Therefore, in Table B, a food with a pH value less than 4.2 is considered non-PHF/non-TCS Food regardless of its water activity.

The lowest water activity value that will allow toxin production of Staphylococcus aureus is 0.88. As noted for Table A, the lowest a_w value to inhibit growth and toxin production for Clostridium botulinum, Clostridium perfringens, and Bacillus cereus is 0.93. Therefore, in Table B, a food with an a_w value of less than 0.88 is considered non-PHF/non-TCS Food regardless of its pH.

It is important to note that regardless whether using Table A or Table B, if further Product Assessment is required the food must be treated as a PHF/TCS Food until proven otherwise. More information for microbiological challenge studies can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.cfsan.fda.gov/~comm/ift4-toc.html.

EXAMPLES OF USING THE TABLES TO DETERMINE WHETHER A FOOD IS A PHF/TCS FOOD

Cut Melons:

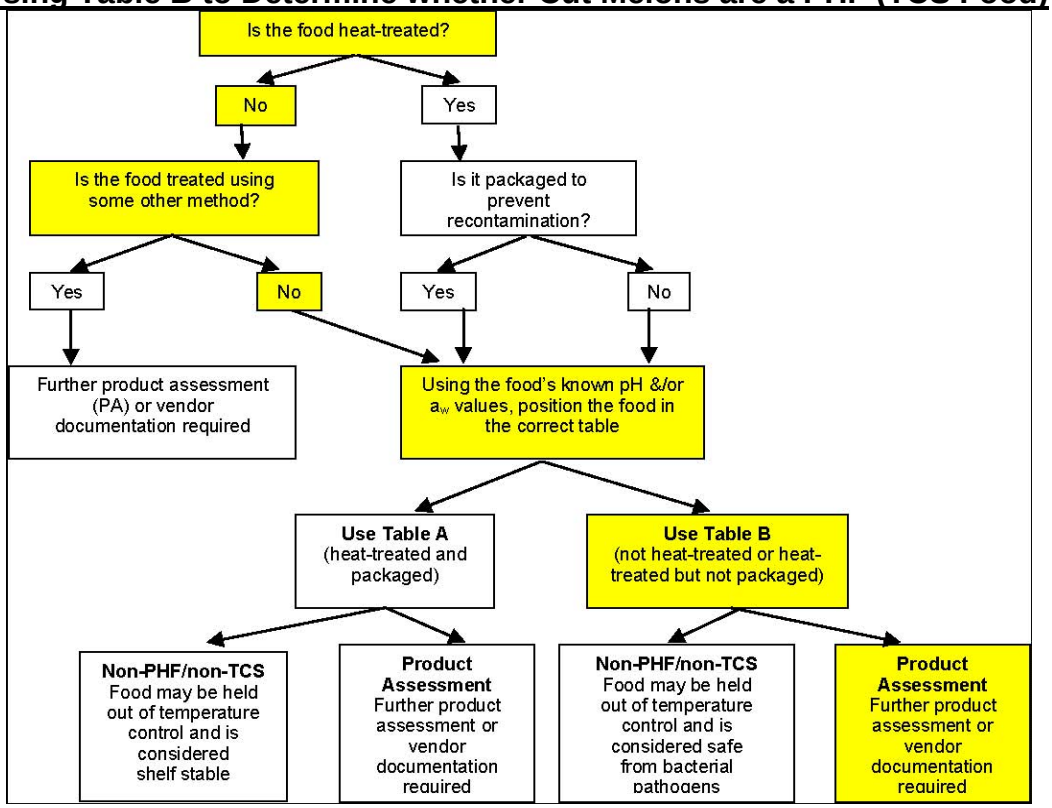
Cut melons are an example of fruits that are considered potentially hazardous once the outer rind has been penetrated. Infiltration studies have shown that pathogens are able to enter the stem end of cantaloupes, as well as through bruises and cankers. This is especially true when water containing the contaminants is more than 10° F cooler than the melons themselves. The air cell in the center of the melon contracts and creates a vacuum which pulls contamination in through damaged areas of the rind and through the stem end.

Also, the contaminated surfaces of the melons, utensils, equipment, and hands can serve as vehicles of contamination to the cut surface of the melon where nutrients and moisture allow the foodborne pathogens to grow. The internal pH values of honeydew melon, watermelon, and cantaloupe are 6.3 to 6.7, 5.2 to 5.6, and 6.2 to 7.1, respectively. The water activity value of all of these melons is greater than 0.99.

Cut melons are not usually heat-treated to destroy pathogens, and no other antimicrobial process can be applied to the cut surface once it is contaminated. In addition, unrefrigerated cut melons have been implicated in several foodborne outbreaks.

If the pH and a_w values of cut melons are positioned in Table B, cut melons are designated as "PA," or Product Assessment Required. This means that until laboratory studies show that the cut melons do not support the growth and/or toxin production of pathogens, they should be treated as PHF/TCS Food and require time/temperature control for safety.

Using Table B to Determine whether Cut Melons are a PHF (TCS Food)



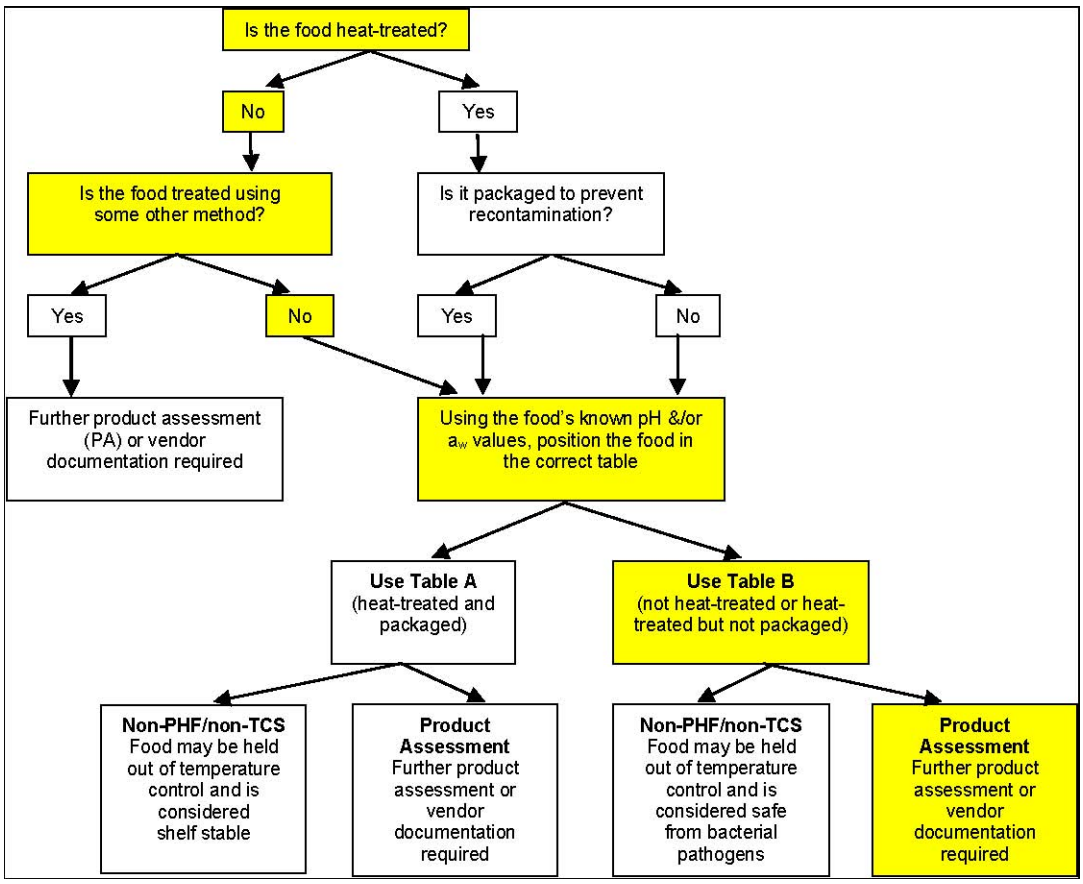
Raw Seed Sprouts:

Sprouted seeds often come in to the sprouter as an agricultural commodity and not as a food. Even though only a very small percentage of the seeds may be contaminated with foodborne pathogens, the continuous irrigation of the seeds during the sprouting process will contaminate all the sprouts in the lot. In addition, there is no fully effective way of eliminating all pathogens from the seeds before sprouting or from the sprouts themselves after sprouting since pathogens are sometimes taken up into the tissue of the sprout from the roots.

Heat-treatment is not generally applied to raw sprouts, and no antimicrobial products appear totally effective on the sprouts. A 20,000 ppm calcium hypochlorite solution seems to be fairly effective on the seeds before sprouting, but foodborne outbreaks continue.

The pH and water activity values of raw seed sprouts, > 6.5 and > 0.99, respectively, do not prevent pathogen growth. If the pH and a_w values of raw seed sprouts are positioned in Table B, raw seed sprouts are designated as "PA," or Product Assessment Required. This means that until laboratory studies show that the raw seed sprouts do not support the growth and/or toxin production of pathogens, they should be treated as PHF/TCS Food and require time/temperature control for safety.

Using Table B to Determine whether Raw Seed Sprouts are a PHF (TCS Food)



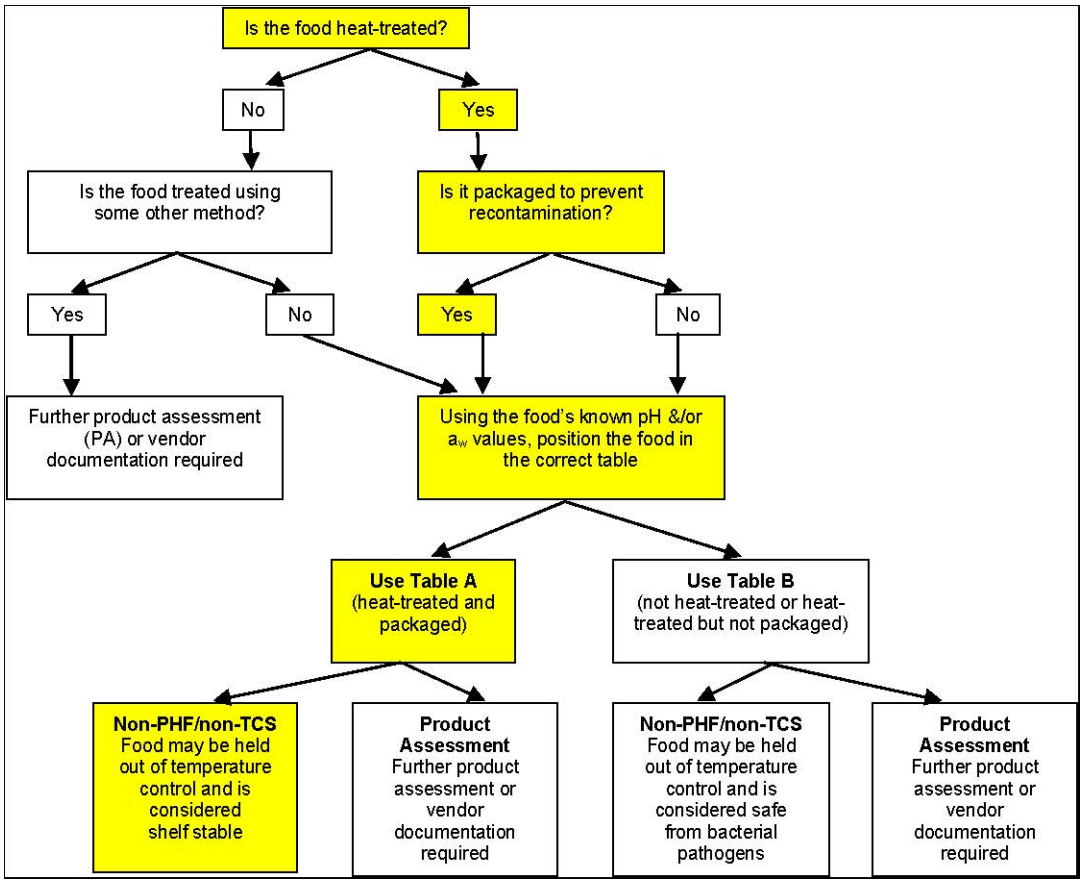
Parmesan Cheese:

Parmesan cheese is processed by heating curd to ~130° F, followed by 2 – 3 years of curing to remove moisture. The cheese is then packaged. The a_w value of parmesan cheese is 0.68 – 0.76, whereas the pH value is around pH 6.5. This product meets a Standard of Identity for hard cheeses.

There has been no history of foodborne illness related to this product. In addition, this product has traditionally been stored at ambient room temperature.

If the pH and a_w values of parmesan cheese are positioned in Table A, parmesan cheese is designated as "Non-PHF/Non-TCS Food." This means that no time/temperature control is required to ensure safety.

Using Table A to Determine whether Parmesan Cheese is a PHF (TCS Food)

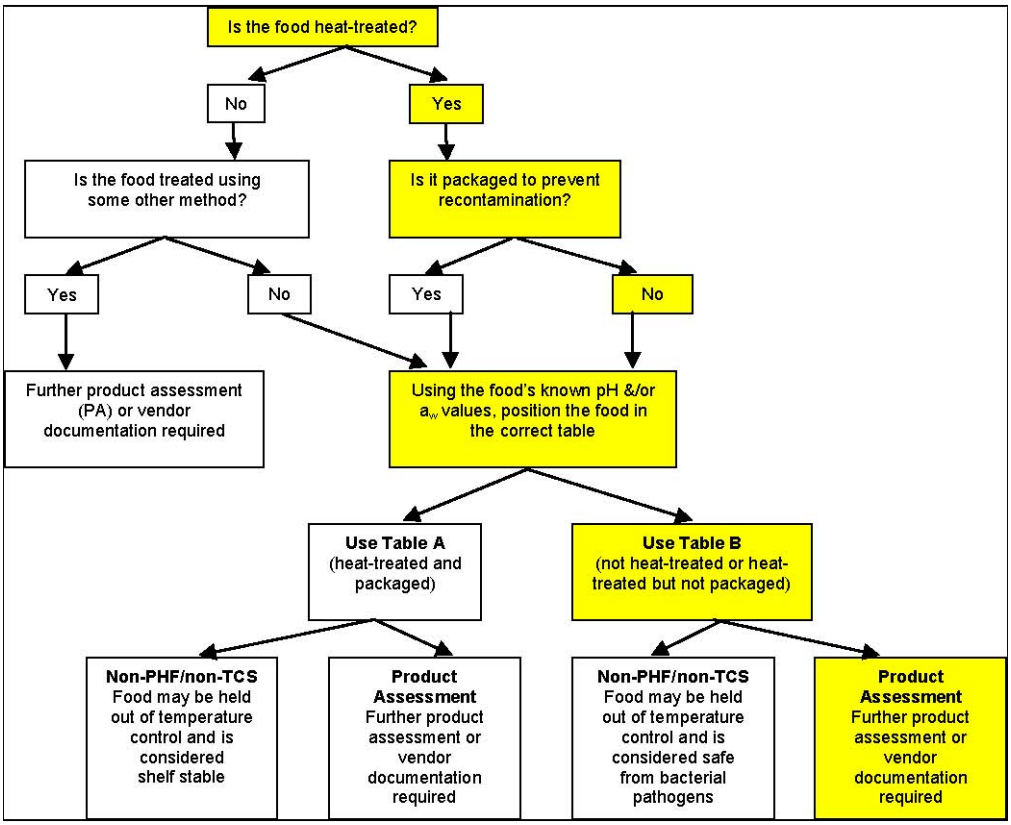


American Processed Cheese Slices:

American processed cheese slices are good examples of products which may require additional product assessment before a final determination can be made. The a_w value of American processed cheese slices is 0.94 – 0.95, whereas the pH value is between 5.5. and 5.8. This product is heat-processed, then packaged into loaves and transported under refrigeration to retail and food service establishments. The cheese packaging is opened once it reaches food service establishments and the cheese slices are stored in containers until used in preparation of sandwiches.

Based on this information, Table B would be chosen because there is potential that the product may become recontaminated. If the pH and a_w values of American cheese slices are positioned in Table B, the cheese is designated as "Product Assessment Required." This means that time/temperature control for safety is required unless laboratory studies show that the cheese does not support the growth and/or toxin production of pathogens.

Using Table B to Determine whether American Processed Cheese Slices are a PHF (TCS Food)



A major corporation wants to be able to store American processed cheese slices at room temperature for a limited period of time because the refrigerated cheese slices cool the hamburger patties in their sandwiches too quickly, making them unappetizing to customers. Ambient storage for limited periods of time was desired. A well-designed challenge test was conducted by the company. Four different pathogens were used. There was no growth for 24 hours when stored at 86° F, and no growth for 210 days when stored under refrigeration.

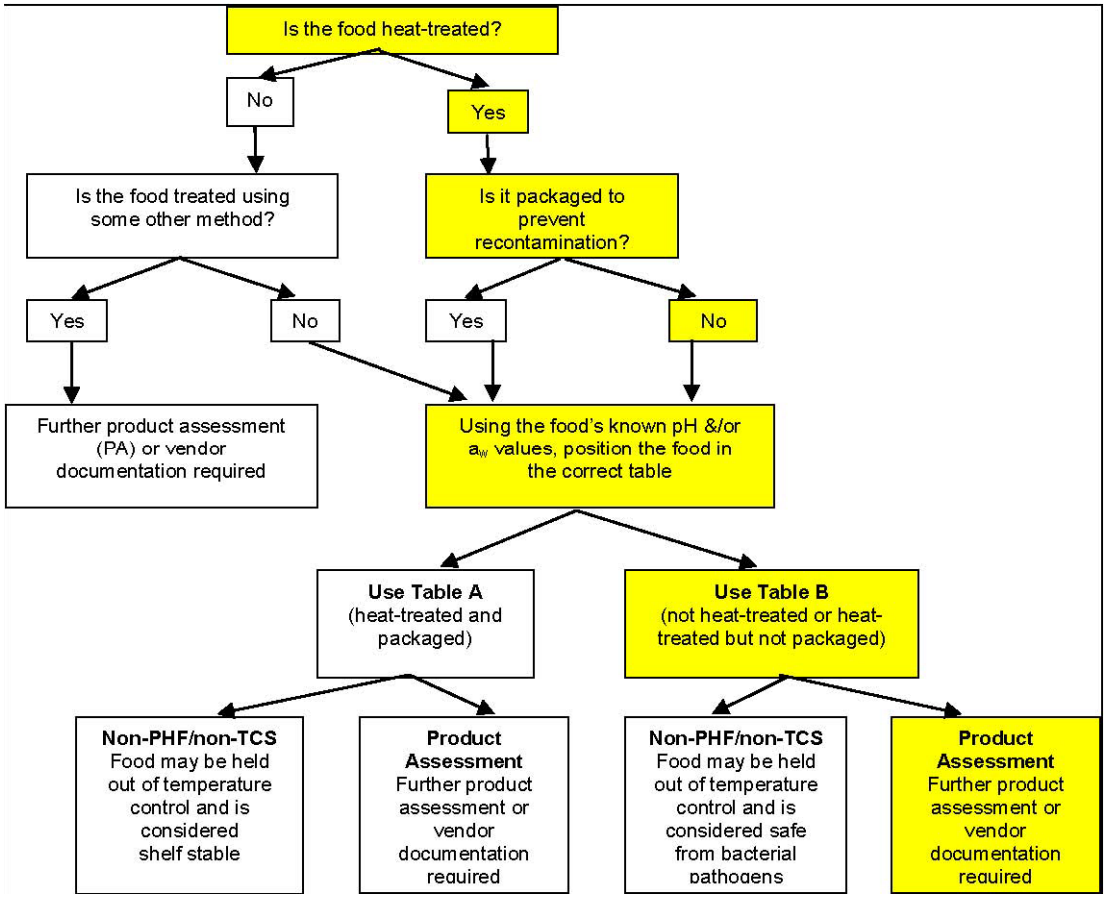
Although the cheese slices are not considered Non-PHF/Non-TCS, they may be safely held out of temperature control for 24 hrs., provided the ambient temperature does not exceed 86° F and provided that the cheese used is from one of the two suppliers used in the inoculation study.

Focaccia Bread:

In the case of combination products, there are two or more distinct food systems. These products require special consideration. Components with significantly different pH or a_w produce an altered microenvironment at the interface, possibly resulting in unexpected pathogen behavior. Microbiological challenge studies will be necessary to determine if the product is a PHF/TCS Food or Non-PHF/Non-TCS Food. All combination products should be treated as a PHF/TCS Food until proven otherwise.

Focaccia bread is one such product that is processed separately and assembled later. The retail food establishment may layer the bread with meats, cheeses or vegetables and hold for display purposes.

Using Table B to Determine whether Focaccia Bread is a PHF (TCS Food)

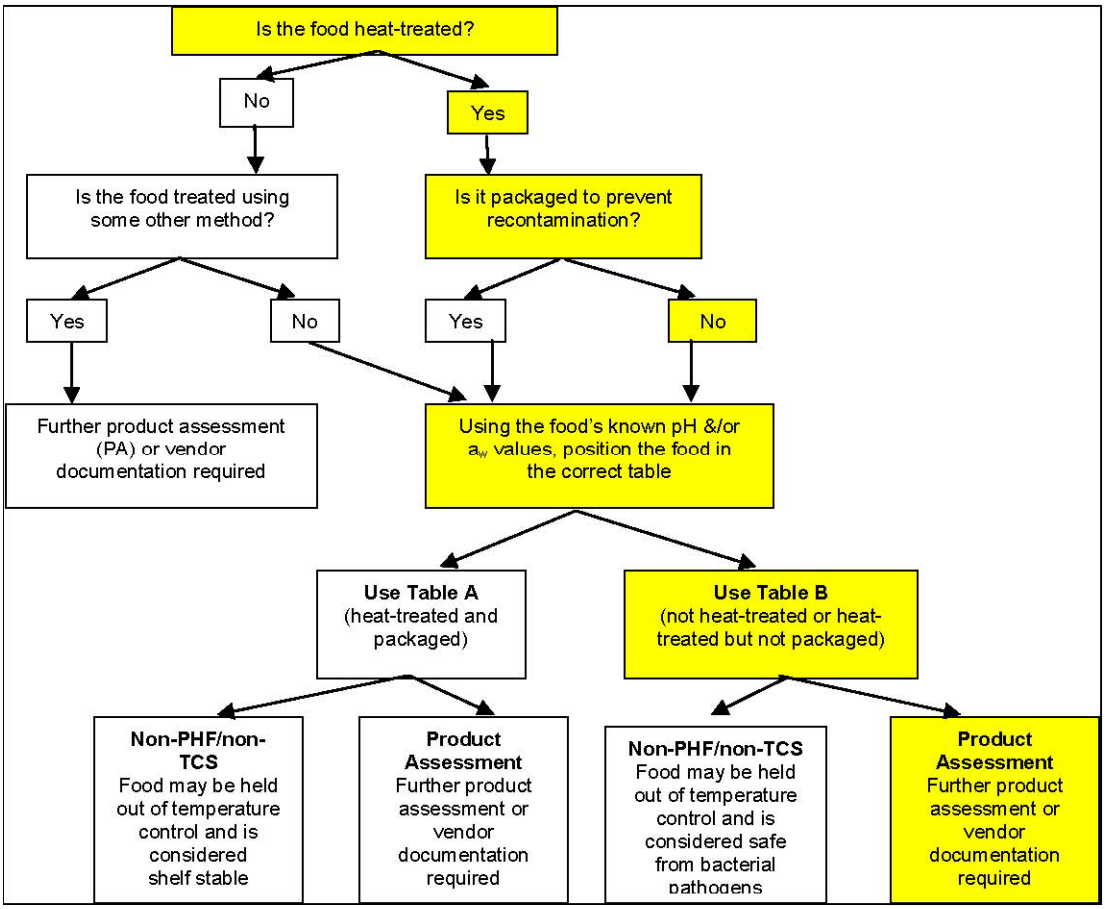


Sushi Rice:

Sushi rolls with raw fish are food that may be encountered at room temperature. The cooked rice or sticky rice used to make sushi rolls has a water activity of 0.98 – 0.99 and a normal pH of 6.0 – 6.7. After acidification by sweetened rice wine vinegar, the pH is usually about 4.2. The pathogen of concern with rice is Bacillus cereus, which has a limiting pH of 4.9 and a water activity of 0.93 for growth and toxin production. The pH of 4.2 makes the rice non-PHF.

However, if raw fish products are added to the sushi rice, any pathogens in the raw fish are not controlled by the acidified rice. The interface between the rice and the raw fish may have a different pH and a_w. The acidified rice does not control pathogens in the raw fish for which the combination of pH and water activity shows the food to require PA or be treated as a potentially hazardous food (TCS food). A product assessment would be required if raw fish is added to the sushi rice or time/temperature control for safety could be used as the public health control.

Using Table B to Determine whether Sushi Rice With Raw Fish is a PHF (TCS Food)

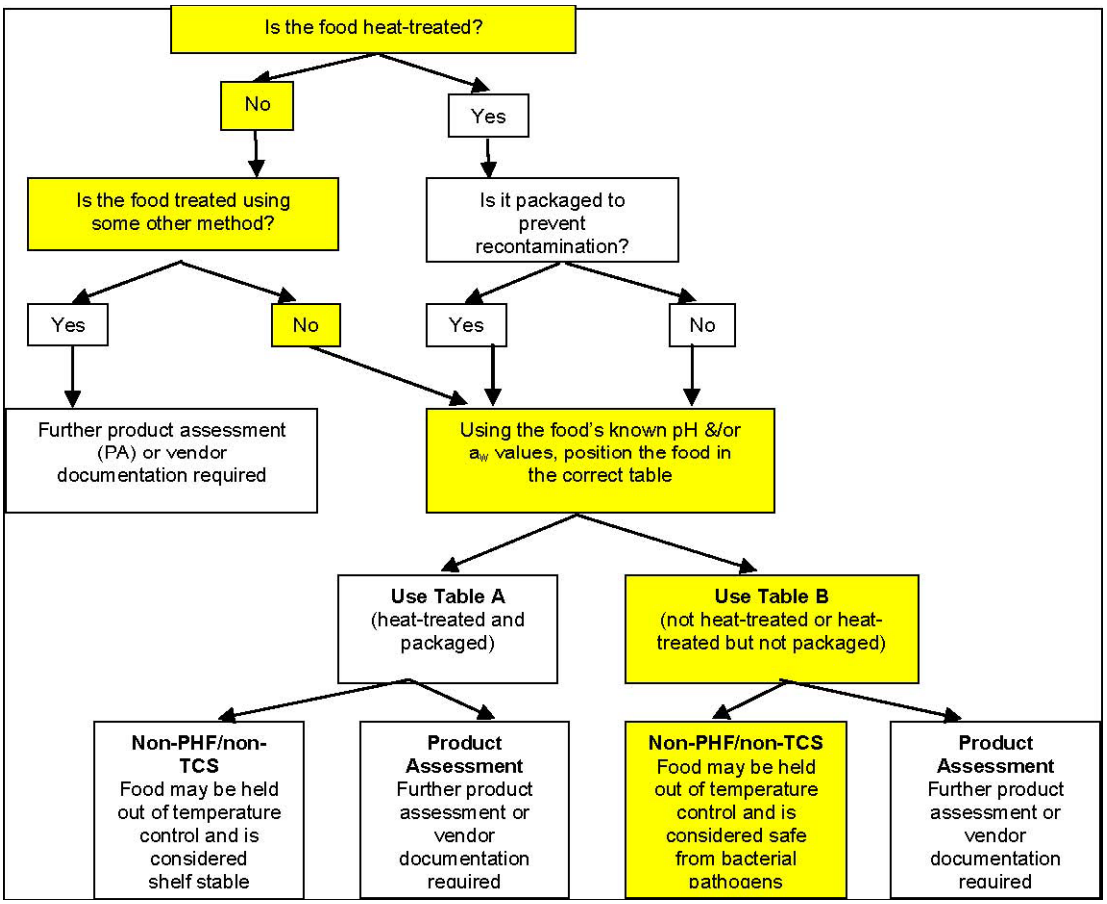


Salad Dressing/Sauce:

The product is manufactured in a tank using a blend of soybean oil, water, pasteurized egg yolks, preservatives, salt and seasonings which are blended at high speeds until an emulsion is established. The product is then portion packed into individual serving sizes and stored until distribution to the retail food establishment. The product is formulated to have a pH value between pH 3.6 and 4.4. The a_w value is < .85.

The product is considered to be shelf stable and can be stored at ambient room temperatures. The retail food establishments may refrigerate for quality purposes. However, if a salad dressing/sauce containing an ingredient like eggs, in which time/ temperature control for safety is necessary and is manufactured on site at the retail food establishment, a variance and HACCP plan would be required.

Using Table A to Determine whether Salad Dressing/Sauces are a PHF (TCS Food)



WHEN IS LABORATORY EVIDENCE LIKELY TO BE USED?

Laboratory evidence is likely to be submitted to the regulatory authority in the following scenarios:

- When the pH and water activity values indicate PA (Product Assessment) required in the Interaction Tables.
- A variance application is submitted for processing or handling food in a manner not specifically allowed by the Texas Food Establishment Rules.
- When preservatives such as nitrites are added to food to inhibit the growth of microorganisms.
- When new technologies such as ozonation are used, and there is no letter of guarantee from the manufacturer.
- For determining whether or not certain multi-ingredient or combination foods, such as sushi rolls with raw fish, or stuffed/topped bakery products require time/temperature control for safety. Such foods are not homogeneous, and the interface between the distinct food components must be evaluated separately from the individual components.
- When the intent is to no longer hold a food under time/temperature control but to store it at ambient temperature.

Inoculation studies or challenge tests must be designed, implemented, and evaluated by an expert microbiologist. Failure to account for differences in products, environmental factors, characteristics of the methodology, or pathogens could result in a flawed conclusion because of incomplete or inaccurate information. For this reason, a competent laboratory should be ustilized. Most independent laboratories have expert microbiologists on staff to help design the study.

Before designing the study, it is necessary to know whether the objective of the study is to show that a food is a non-PHF/non-TCS food or whether the objective is to be able to store the food without temperature control for a certain length of time. In addition, it is vital to know the intended use of the product and the specific conditions under which the product is used and stored in the establishment.

It may be necessary to consult with microbiologists or other food science or food technology experts at universities or federal agencies to help with evaluating the design, methodology, and results of the study.

When evaluating the results of an inoculation study, it is essential that the appropriate challenge organisms were chosen, the design of the study considered all necessary factors and that the study was designed and evaluated by an expert microbiologist familiar with food chemistry and foodborne pathogens. If the study was designed and implemented properly, it will indicate whether the challenge organisms died, their numbers did not change, or their numbers increased. It should also indicate if any toxin-producing pathogens formed toxin in the food under the conditions studied. If the data show that foodborne pathogens grow during the test period, options include reformulating the food to allow safe holding at ambient temperatures or choosing a shorter time that the food may be held without temperature control.