Texas Health and Human Services

Texas Department of State Health Services

Consumer Protection Division
Policy, Standards, And Quality Assurance Section Public Sanitation And Retail Food Safety Unit

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, and results from laboratory testing for pH and aw, 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 non-TCS Food or held under temperature control for safety.

INTERACTION TABLES

Two Interaction Tables were added to the 2005 FDA Food Code that use the values of pH and water activity in a food to determine if the food is non-TCS Food because of its pH or water activity alone or the interaction of the two factors. When the pH and aw combination does not result in the classification of the food as non-TCS Food, further product assessment (PA) is required. In the meantime, the food must be treated as 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. This concept involves the use of several inhibitory factors, or hurdles, to inhibit pathogen growth, which when used alone, would be ineffective.

Table A. Interaction of PH and AW for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_W values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
<0.92	NTCS FOOD*	NTCS FOOD	NTCS FOOD
> 0.92 - 0.95	NTCS FOOD	NTCS FOOD	PA**
> 0.95	NTCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOOD
** PA means Product Assessment required

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 TCS Food or 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 aw or pH.
- To eliminate vegetative pathogens, the food must be cooked for the required time and temperature specified in §25 TAC 228.71 (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 the 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 aw 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-TCS Food regardless of its water activity (see column under pH 4.6 or less – all 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 aw = 0.92 or less is considered non-TCS Food regardless of its pH.

Table B. Interaction of PH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_W values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	NTCS food*	NTCS food	NTCS food	NTCS food
0.88 – 0.90	NTCS food	NTCS food	NTCS food	PA**
> 0.90 – 0.92	NTCS food	NTCS food	PA	PA
> 0.92	NTCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOOD
** PA means Product Assessment required

Table B considers the "Interaction of pH and aw 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 TCS Food or 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 4.2. This value is close to 4.4 for *Listeria monocytogenes*. Therefore, in Table B, a food with a pH value less than 4.2 is considered 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 aw 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-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 TCS Food until proven otherwise.

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

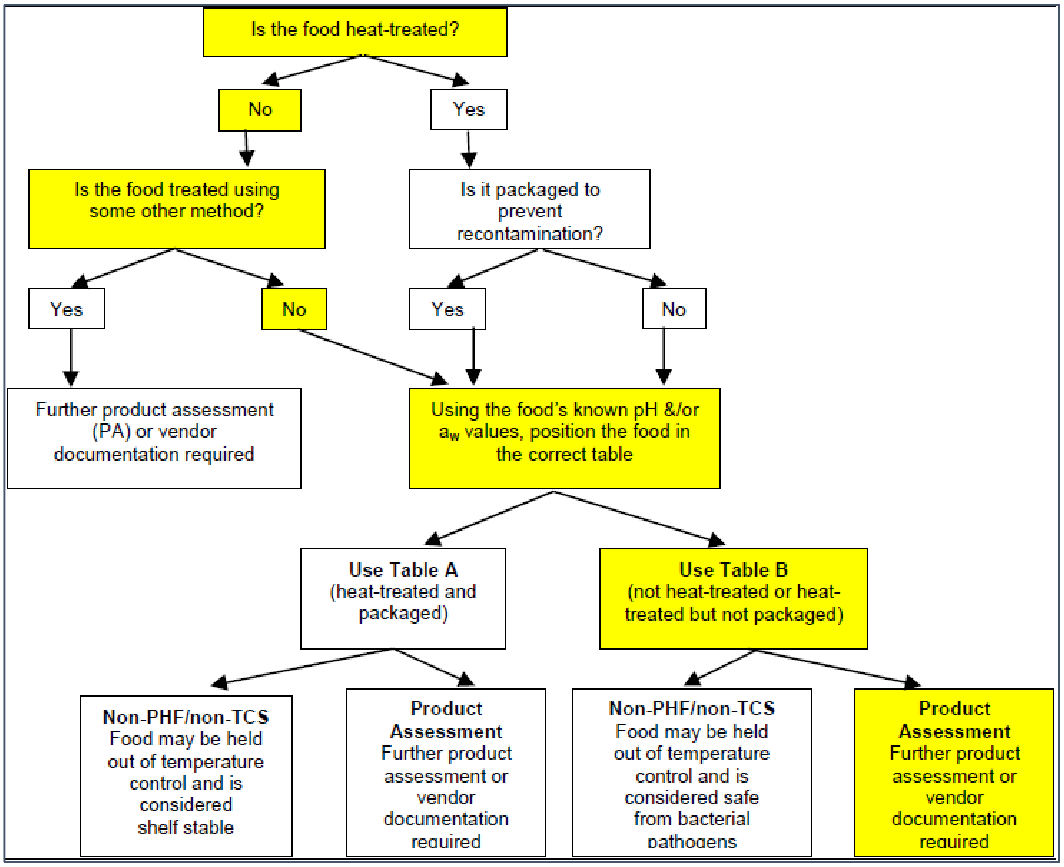
Cut Melons:

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 a vehicle 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 also been implicated in several foodborne outbreaks. If the pH and aw 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 TCS Food and require time/temperature control for safety.

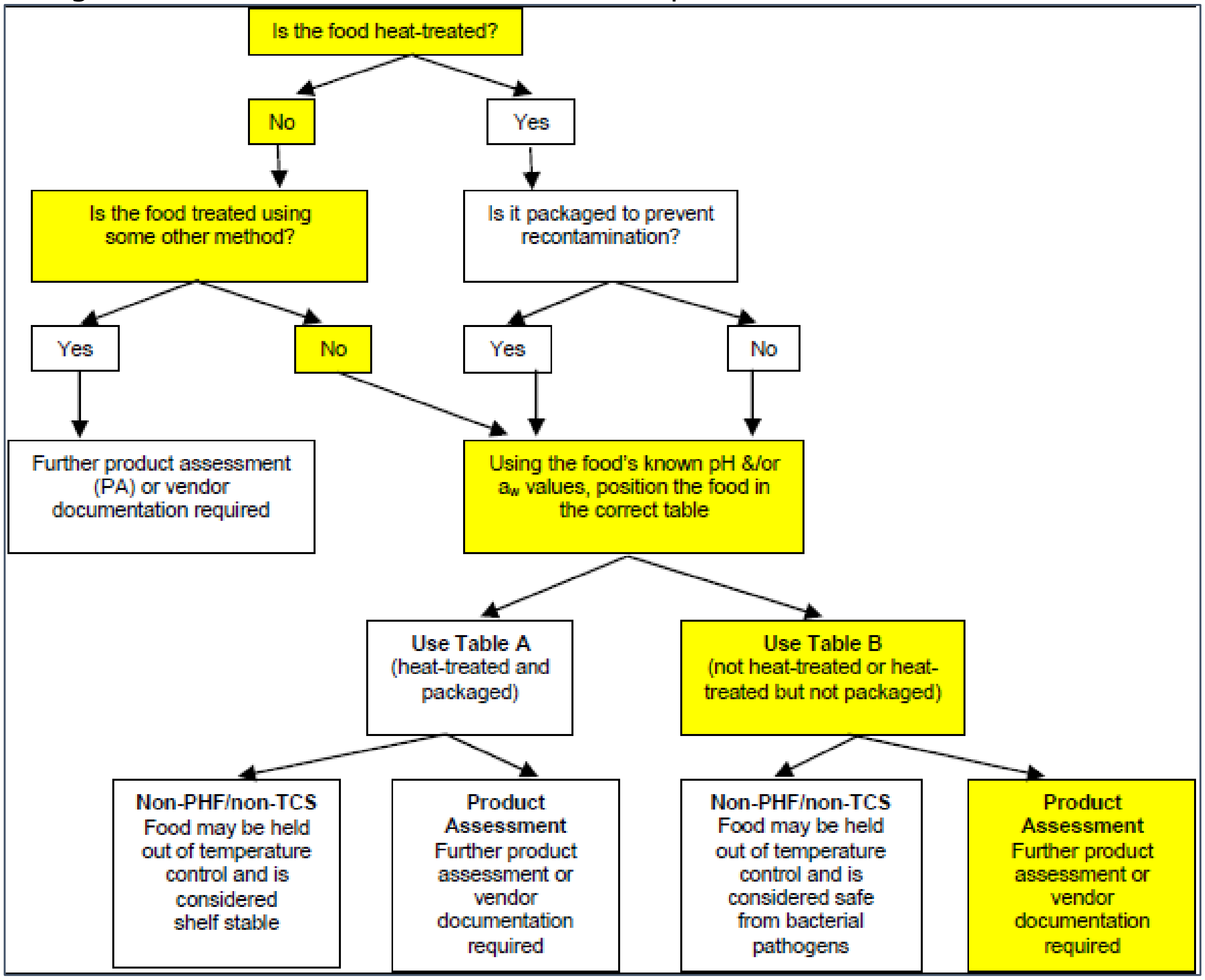
Using Table B to determine if cut melons are TCS



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.

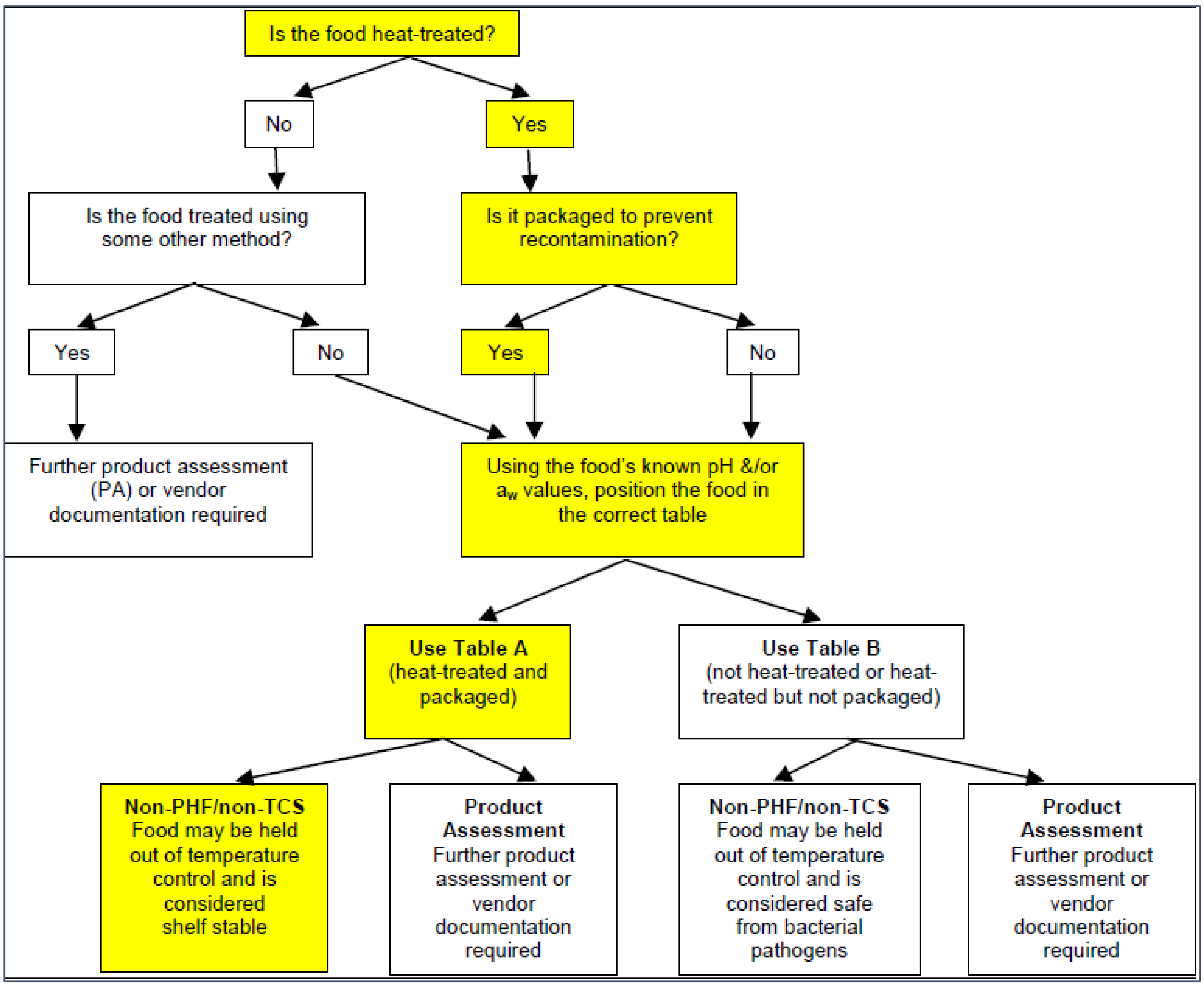
Heat-treatment is not generally applied to raw sprouts, and no antimicrobial products appear totally effective on the sprouts. A 20,000 ppm calcium hypochlorite solution seems to be fairly effective on the seeds before sprouting, but foodborne outbreaks continue. The pH and water activity values of raw seed sprouts, > 6.5 and > 0.99, respectively, do not prevent pathogen growth. If the pH and aw 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 TCS Food and require time/temperature control for safety.

Using Table B to determine if Raw Seed Sprouts are TCS



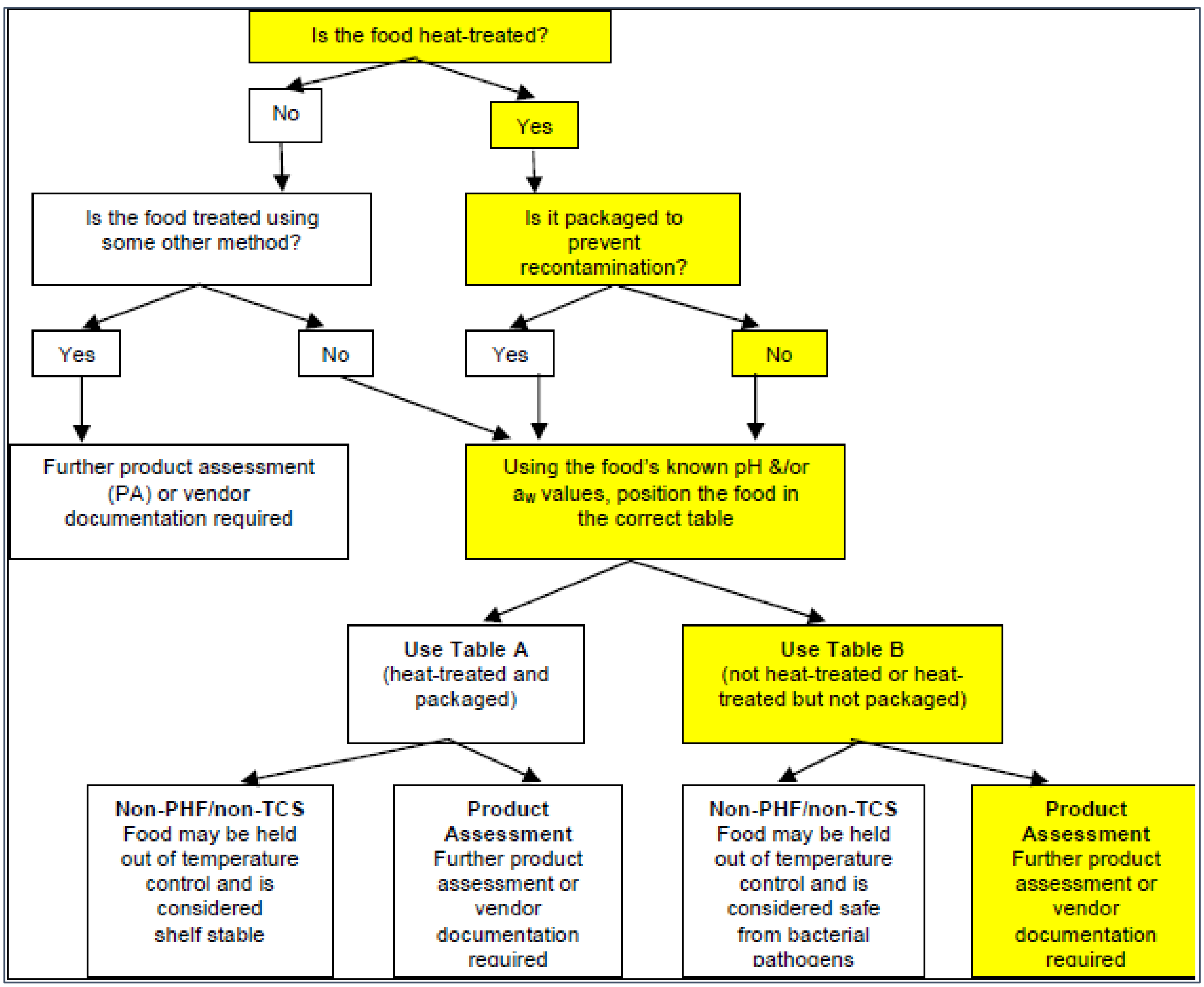
Parmesan Cheese:

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 aw value of parmesan cheese is 0.68 – 0.76, whereas the pH value is around 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 aw values of parmesan cheese are positioned in Table A, parmesan cheese is designated as "Non-TCS Food." This means that no time/temperature control is required to ensure safety.



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 aw 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 TCS Food or Non-TCS Food. All combination products should be treated as a TCS Food until proven otherwise.

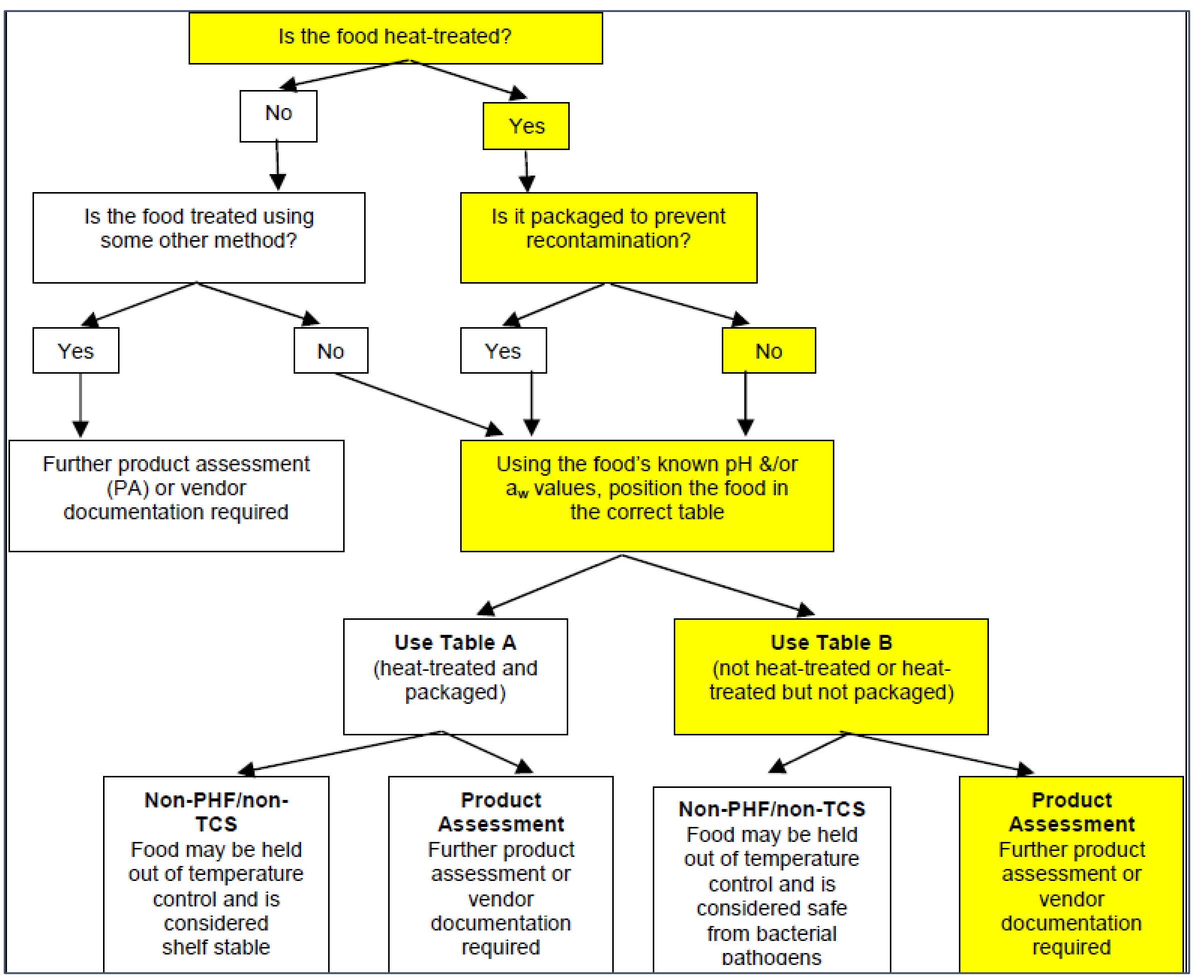
Focaccia bread is one such product that is processed separately and assembled later. The retail food establishment may layer the bread with meats, cheeses or vegetables and hold for display purposes.



Sushi Rice:
Sushi rolls with raw fish is 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-TCS. But 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 aw.

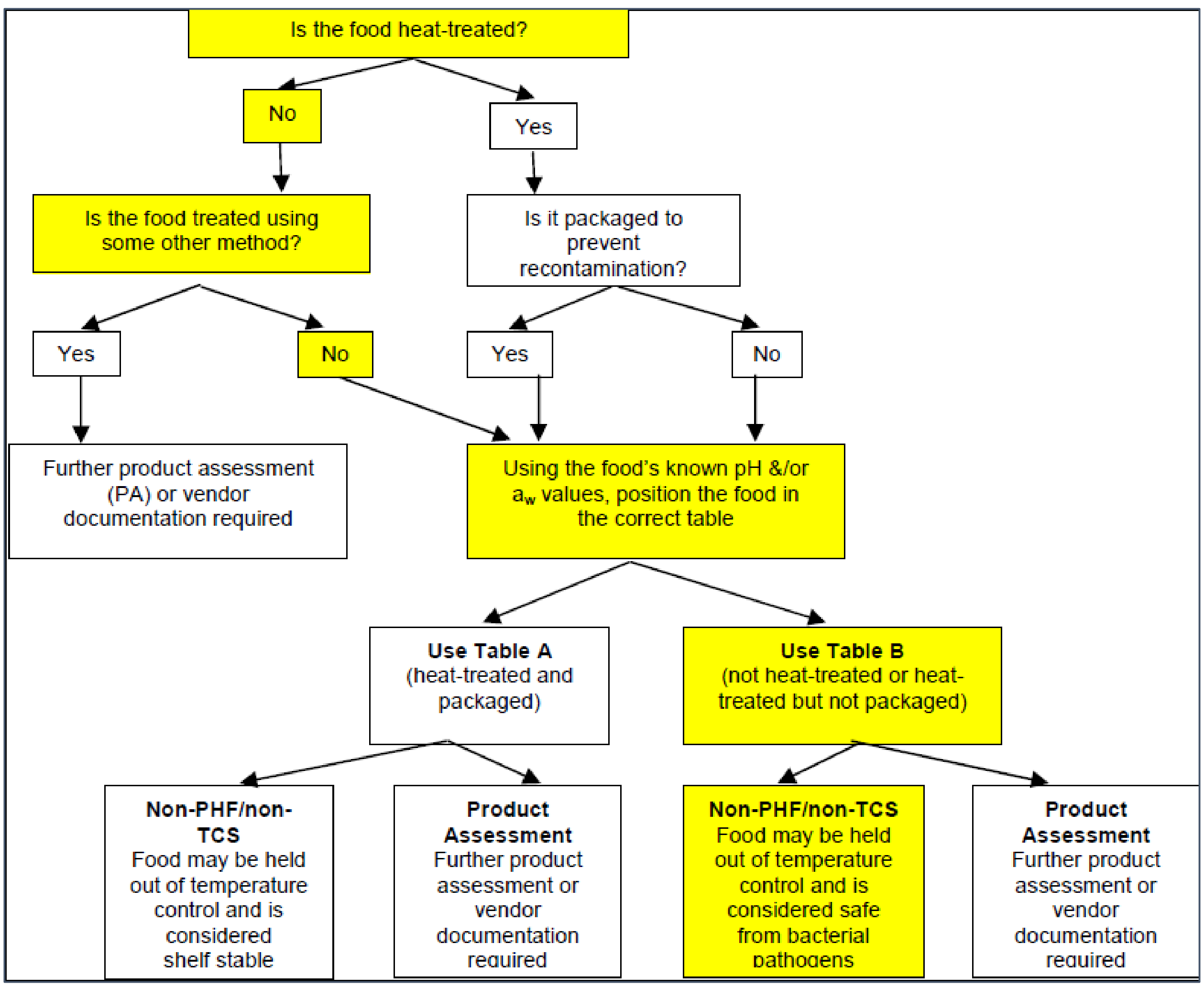
The acidified rice does not control for pathogens in the raw fish for which the combination of pH and water activity shows the food to require PA or be treated as a TCS food. A product assessment would be required if raw fish is added to the sushi rice or time/temperature control for safety could be used as the public health control.

Using Table B to Determine whether Sushi Rice is a 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 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 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 Food Code.
- 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 needs to 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 testing 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 used. 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-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 without temperature control.