

APPENDIX A - Potentially Hazardous Foods

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 term does not include foods that do not support growth but may contain a pathogenic 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 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 destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 135°F (57°C). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a PHF/TCS food.

A well designed inoculation study 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 (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or
- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, and antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B listed in the definition section under item 79 for "potentially hazardous food (time/temperature control for safety food)" in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
 - If the answer is No, no further action is required. The decision tree later in this Appendix 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 utilizing the definition of "potentially hazardous food (time/temperature control for safety food)"?
- Does a product history with sound 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 high temperature (UHT) creamers or shelf-stable canned goods?
- 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?

A food designated as product assessment required (PA), in either table should be considered PHF/TCS Food until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered PHF until inoculation studies or some other acceptable evidence shows that the food is a PHF/TCS food or not. The Rules and Regulations require a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

The Rules and Regulations definition designates certain raw plant foods as PHF/TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat-treated), fresh sprouts (pH > 6.5 , $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 - 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for PHF/TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a HACCP plan and approval from the department is required under 3-606. A HACCP plan is required whether the food is a PHF/TCS food as in Section 3-606 (A)(3)(a) of these rules and regulations or not a PHF/TCS food, as in Section 3-606(A)(3)(a) of these rules and regulations. A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the approval process with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
 - a. No - Continue holding the food at $\leq 41^\circ\text{F}$ (5°C) or $\geq 135^\circ\text{F}$ (57°C) for safety and/or quality.
 - b. Yes - Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
 - a. No - The food is either raw, partially cooked (not cooked to the temperature specified in section 3-502 of the Rules and Regulations) or treated with some other method other than heat. Proceed to step #3.
 - b. Yes - If the food is heat-treated to the required temperature for that food as specified under section 3-502 of the Rules and Regulations, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?

- a. No - The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
 - b. Yes - If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
- a. No - Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
 - b. Yes - If the food is packaged immediately 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 hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
- a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.
 - b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.
6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
- a. Choose the column under "pH values" that contains the pH value of the food in question.
 - b. Choose the row under " a_w values" that contains the a_w value of the food in question.
 - c. Note where the row and column intersect to identify whether the food is "non-PHF/non-TCS food" and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.
7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).

**DECISION TREE #1 - USING pH, A_w , OR THE INTERACTION OF
pH AND A_w TO DETERMINE IF A FOOD REQUIRES
TIME/TEMPERATURE CONTROL FOR SAFETY**

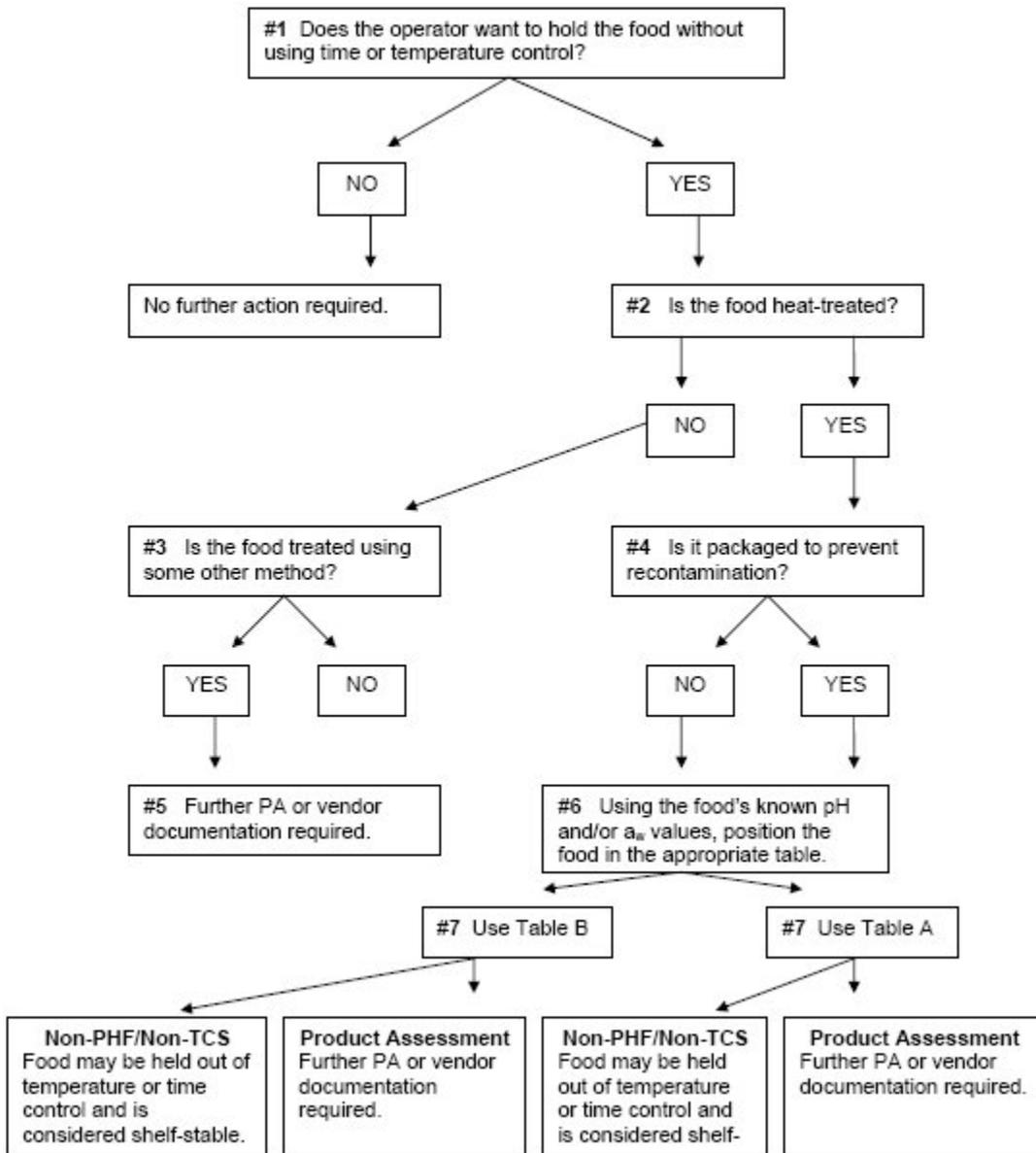


TABLE A AND TABLE B

TABLE A. INTERACTION OF PH AND A_w FOR CONTROL OF SPORES IN FOOD HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED			
A_w VALUES	<u>PH VALUES</u>		
	4.6 OR LESS	> 4.6 - 5.6	> 5.6
≤ 0.92	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD
> 0.92 - .95	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***
> 0.95	NON-PHF/NON-TCS FOOD	PA	PA

* PHF MEANS POTENTIALLY HAZARDOUS FOOD

** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

*** PA MEANS PRODUCT ASSESSMENT REQUIRED

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	<u>PH VALUES</u>			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	NON-PHF*/ NON-TCS FOOD**	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD
0.88 - 0.90	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA***
> 0.90 - 0.92	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA	PA
> 0.92	NON-PHF/ NON-TCS FOOD	PA	PA	PA

* PHF MEANS POTENTIALLY HAZARDOUS FOOD

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The following is a limited list of specific food products that have been classified to be potentially hazardous.

1. Bacon - If it has not been fully cooked.
2. Balutes - Fertile eggs, generally chicken or duck eggs, which are incubated for a period of time shorter than is necessary for hatching. The developing embryo is incubated generally 14 to 18 days and is considered a delicacy by various ethnic populations when eaten raw or cooked.
3. Beans - All types of cooked beans.
4. Whipped Butter - Hazardous because of the apparent reduced microbiological safety factor created by whipping.
5. Cheese - Soft unripened cheese. Ripened, low moisture hard cheese such as wheels, flats, blocks or longhorns of cheddar cheese produced from pasteurized milk, when waxed or packaged in "shrink" wrapping with the wax or packaging intact, can be safely shipped or stored for a short period of time without refrigeration but it is not recommended. If wheels, flats, blocks,

longhorns, or any other forms of cheese have been damaged, cut and repackaged for display and/or sale, thereby exposing interior surfaces to possible contamination, the cut portions as well as the remaining cheese shall be held under refrigeration.

6. Coffee Creaming Agents - All non-dairy coffee creaming agents in liquid form, except aseptically processed ultra high temperature (UHT) liquid coffee creaming agents.
7. Cut Leafy Greens- Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of potentially hazardous food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41°F (5°C) or less inhibits growth and promotes general die off in some pathogens such as *E. coli* O157:H7, *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers.
8. Cut Tomatoes- Historically, uncooked fruits and vegetables, such as cut tomatoes, have been considered non-PHF unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. The US Food and Drug Administration (FDA) has reported that since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes and additionally, from 1998-2006, outbreaks associated with tomatoes made up 17% of the produce related outbreaks reported to FDA nationwide. *Salmonella* has been the pathogen of concern most often associated with tomato outbreaks.
9. Eggs - Cooked, cracked, fresh with outer shell removed, peeled hard-boiled eggs, and hard-boiled eggs with intact shells which have been hard-boiled and then cooled in liquid. Refrigeration of raw whole eggs in the shell is required.
10. Garlic - Garlic in oil products.
11. Mayonnaise or Other Acidified Salad Dressings - If the pH is above 4.6 and/or combined with other food products.
12. Onions- Cooked and dehydrated that have been reconstituted.
13. Pasta - All types that have been cooked.
14. Pastries - Meat, cheese and cream filled.
15. Pies - Meat, fish, poultry, natural cream, synthetic cream, custard, pumpkin and pies that are covered with toppings which will support microbial growth.
16. Potatoes - Baked, boiled or fried.
17. Rice - Boiled, steamed, fried, Spanish and cooked rice used in sushi.
18. Sour Cream - If the pH is above 4.6 and/or combined with other food products.
19. Soy Protein - Tofu and other moist soy protein products.
20. Seed Sprouts - All types.

FOODS WHICH ARE NOT POTENTIALLY HAZARDOUS ARE:

1. Hard-Boiled eggs with shells intact which have been air-dried; and
2. Foods which have been adequately commercially processed and remain in their unopened hermetically sealed container.