TEMPERATURE CONTROLLED FOR SAFETY (TCS) FOOD IMPLEMENTATION COMMITTEE OF COUNCIL I
CFP 2004 - 2006

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CONFERENCE FOR FOOD PROTECTION

Promoting Food Safety Through Collaboration

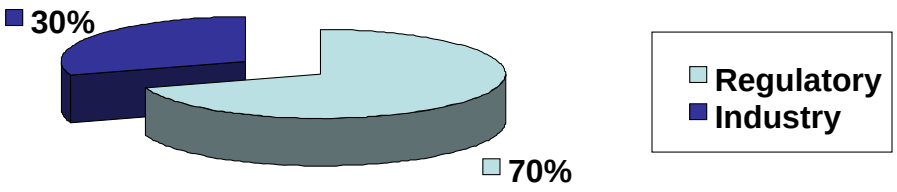
Temperature Control for Safety Committee of Council I

FEEDBACK SURVEY - RESULTS SUMMARY

INTRODUCTION:

The Temperature Control for Safety Committee of Council I of the Conference for Food Protection performed a brief survey of regulatory, industry and academia to determine how the new definition for Potentially Hazardous Foods in the 2005 FDA Model Food Code has been received. Additionally, various other questions regarding clarity of the new definition and decision tree, training needs and possible code adoption by the regulatory jurisdictions were also asked.

There were a total of 57 completed surveys returned – 40 (70%)* by regulatory and 17 (30%) by industry. The following pages comprise a summary of each question and any follow-up questions asked as well as additional comments that were provided by the responder.

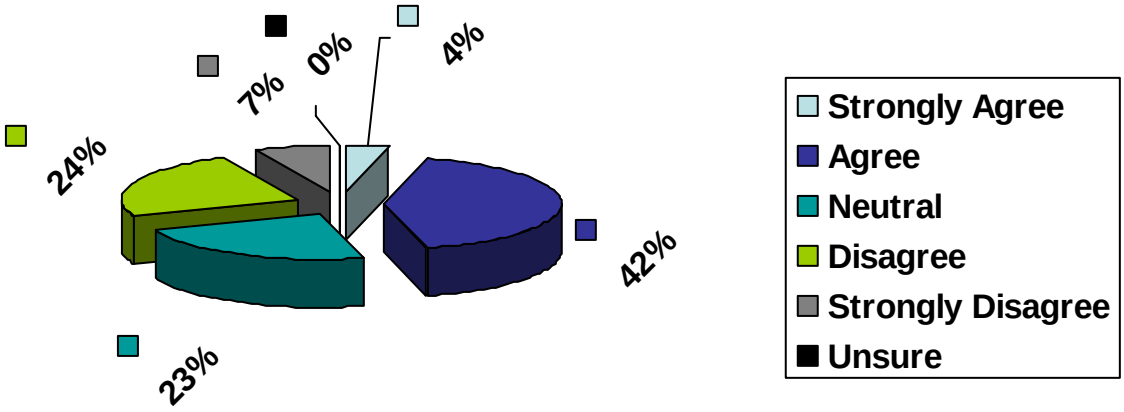


*For the purposes of this survey, fractions were rounded to the nearest percent.

PART 1 – DEFINITION:

QUESTION #1

1. The new definition of PHF/TCS is clear and easily understood.



Follow-up Question 1a: If Disagree, please explain why the term is not clear or understood?

Most common responses: *(see Annex for a complete listing of all comments provided.)*

- Probably would be difficult to understand for an operator.
- I believe the acronym should be TTCS to acknowledge that BOTH time and temperature may be considered. I anticipate confusion on the part of field inspectors.
- The term is clear, the evaluation and lack of product assessment protocol is not clear.
- The definition is quite technical and quite confusing, especially with all of the water activity and pH charts and tables. With some training health inspectors will probably understand, however many food operators will be be quite confused.
- The term is OK, but the charts and actual wording of the definition is not easily understood.

Follow-up Question 1b: What elements, if any, of the new definition need further explanation or training?

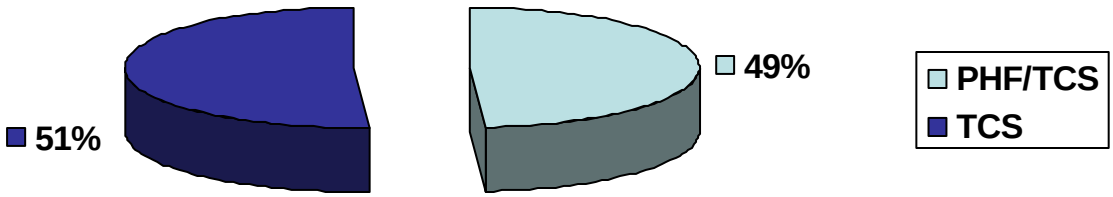
Most common responses: *(see Annex for a complete listing of all comments provided.)*The "title" seems overwhelming – if we want to make it easy to explain to operators and consumers, it's pretty technical.

- The use of the tables would need to be addressed throught training and practice.
- Although the regulatory side will utilize this information, the decision tree is more appropriate for deciding whether to do product assessment or not.
- If I have to use that definition I will have trouble - not a working definition for field inspectors.
- Who is responsible for what?

QUESTION #2

2. Check which term you prefer.

☐ **PHF/TCS Food** ***(The 2005 FDA Food Code will use the combination term, which will be phased out when people are familiar with the new definition.)***
☐ **TCS Food**

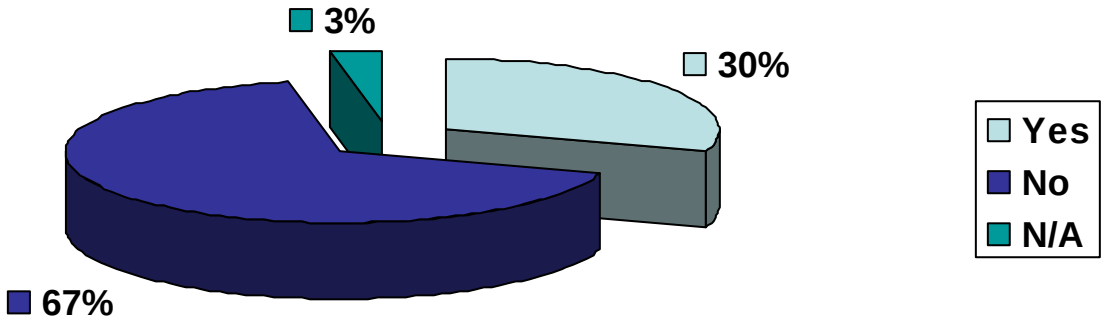


Follow-up Question 2a: Please explain why.
Most common responses: *(see Annex for a complete listing of all comments provided.)*

- PHF is easier to remember. Too many acronyms is confusing.
- Ease of transition for training Opertors
- TCS is very easy to understand. No need to delay transition
- I think it is easier for the industry and the public to understand. It places emphasis on the safety of the food. Potentially hazardous sounds too ominous and the term is misunderstood.
- This gets people thinking about the new concept sooner
- Prefer that the change be made AFTER proper training
- Familiarity with PHF term.
- Will the PHF differ from what they are now?

QUESTION #3

3. Have you had problems in the field with the current definition of PHF?



Follow-up Question 3a: If Yes, please explain?

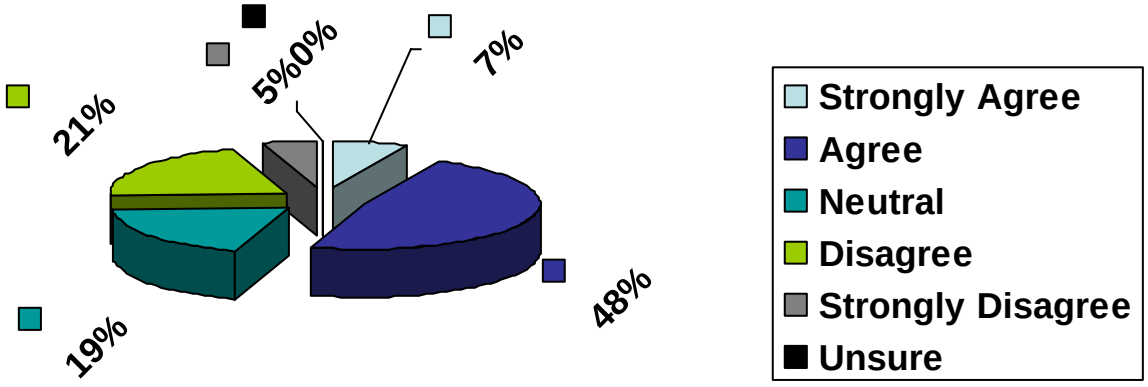
Most common responses: *(see Annex for a complete listing of all comments provided.))*

- The current definition requires refrigeration of products that do not support rapid and progressive growth of pathogens.
- Only because more and more foods fit the definition of TCS; that under the old PHF definition created confusion.
- Generally, no
- Sometimes we are unsure whether foods are potentially hazardous or not.

PART 2 – PHF/TCS DECISION TREE:

QUESTION #1

1. The PHF/TCS Decision Tree is easy to understand.

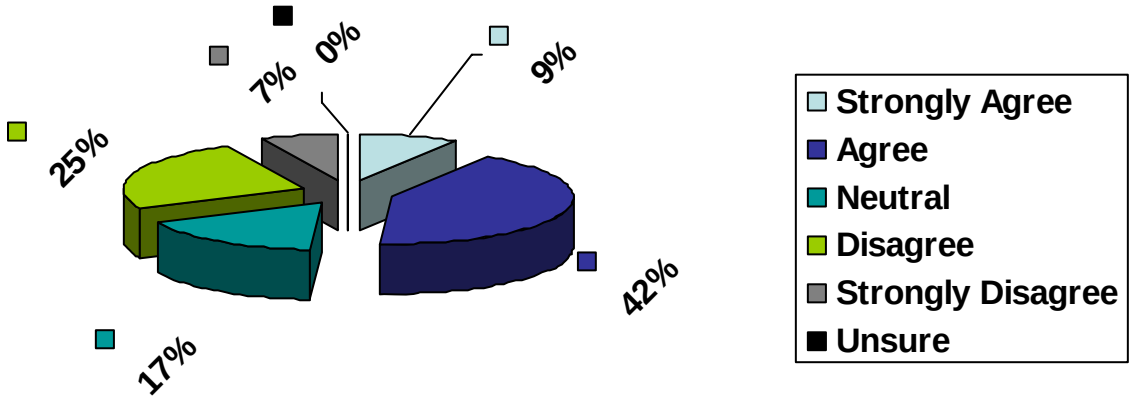


Follow-up Question 1a: If No, please explain why.
Most common responses: *(see Annex for a complete listing of all comments provided.)*

- Without a protocol to evaluate food the the category of prodcut assessment, chart cannot be used. Needs to be a national acceptance body (FDA) to evaluate groups of common food items that are not easily identified using the chart matrix.
- Mostly because it is a new approach that is going to get some getting use to.
- How do we determine pH and aw values in the field?
- Not a field useable tool.
- It is manufacturer's responsibility to make a determination whether his food product is a PHF and must be kept at proper temperature.

QUESTION #2

2. The PHF/TCS Decision Tree is practical and easy to use.



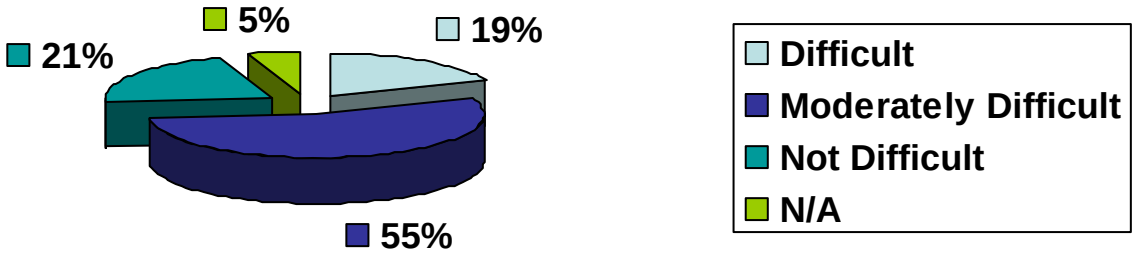
Follow-up Question 2a: If No, please explain why.

Most common responses: *(see Annex for a complete listing of all comments provided.)*

- There will be questions in the field regarding product pH and/or water activity in order to use the Decision Tree.
- Cumbersome and confusing for field application
- Too much time and instrumentation might/will be necessary for practical field application
- To use it you need to know the pH of everything.
- Water activity meters and pH meters introduce concepts most operators are ignorant of.
- If pH or water activity is unknown, then what?

QUESTION #3

3. How difficult do you think the transition will be for your field staff in using the new PHF/TCS definition and Decision Tree?



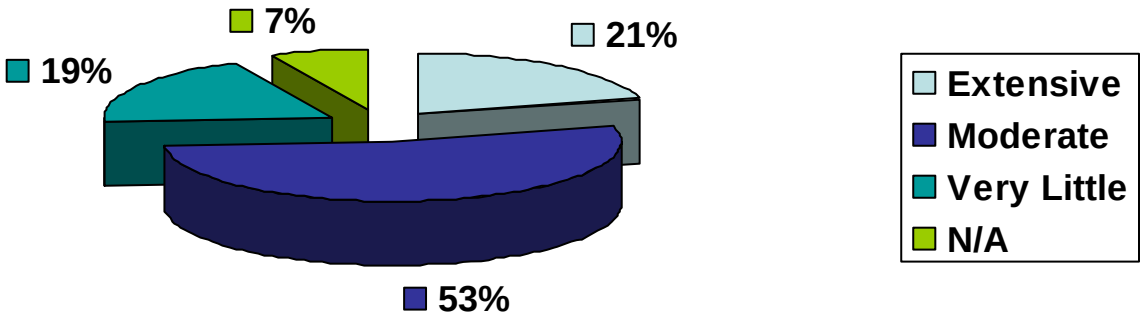
Follow-up Question 3a: If Difficult, please explain?

Most common responses: *(see Annex for a complete listing of all comments provided.)*

- There is are more variables and might be too technical for some to comprehend.
- I THINK THEY SHOULD TRY AND KEEP IT SIMPLE. ON THE LOCAL HEALTH DEPARTMENT LEVEL, IT IS NOT LIKELY THAT WE ARE GOING TO BE ANALYZING DATA SUBMITTED FROM TESTING AGENCIES TO DETERMINE THE PH AND WATER ACTIVITY OF FOODS.
- Some of our staff members have been in the field for years and to make any changes will be met with difficulty. This is not to suggest that the concept of the TCS foods will be difficult, but rather the implementation of the changes into the day-to-day practices of the field staff.
- The new system adds complexity to determining when TCS is needed. All inspectors need new equipment that must be maintained and calibrated.
- Change is always hard.
- Any change, especially one as complex as this will be difficult. State varies on education, experience, etc., which is a factor – different people learn at diverse ratios.
- It is not regulators responsibility in field to do analysis of food products to determine water activity, pH etc. to determine PHF.

QUESTION #4

4. How much training would you need for implementing the new PHF/TCS definition in your jurisdiction?



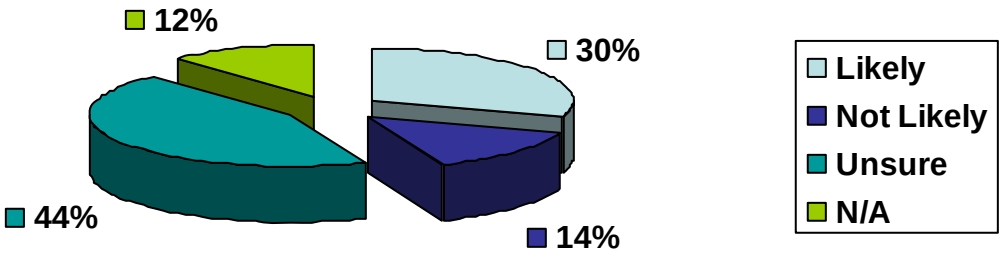
Follow-up Question 4a: What kinds of training would you see as most beneficial – online, workshops, video conference, presentations, etc?

Most common responses: *(see Annex for a complete listing of all comments provided.)*

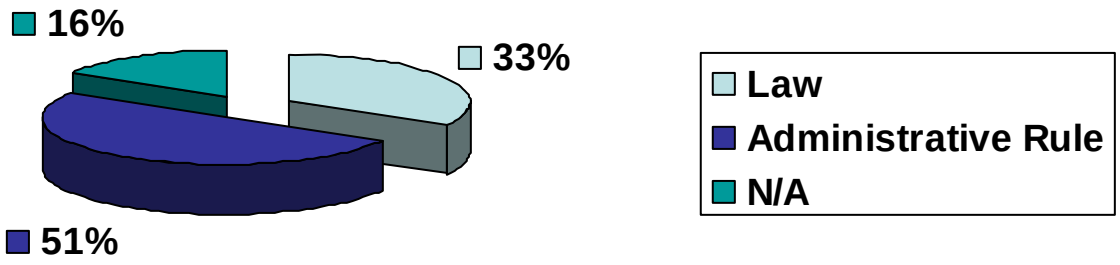
- PRESENTATIONS GIVEN THROUGH OEHA, ODH, OR OTHER REGIONAL FOOD ORGANIZATIONS
- Video conferences
- Workshops or Presentations involving real people. Its makes asking questions a little simpler.
- Online training would be a great benefit because of the geographical spread of our inspectors. Presentations are the next best thing so inspectors can ask questions and don't feel quite so intimidated as at a conference.
- A mixture of field and online workshops would be most beneficial.
- Workshops – hand-on training, tell me, show me, let me do it.
- All of the above.

QUESTION #5

5. How likely are you to incorporate the new definition of PHF/TCS into your jurisdiction?



Follow-up Question 5a: What process would be necessary?

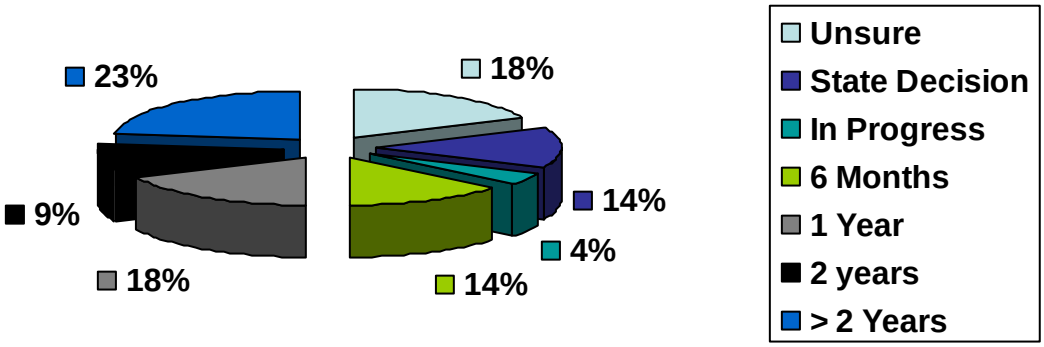


Follow-up Question 5b: What would be the expected timeframe?

Most common responses: *(see Annex for a complete listing of all comments provided.)*

- 3-4 years
- 6 months
- Unsure
- A few years. We just adopted the 2001 FC.
- 1 year
- Decisions made at state level
- Next food code revision (2-3 years)
- Working on adoption of 2005 code currently.
- Years.

Total State Responses - 44



ADDITIONAL COMMENTS:

- Proposed definition overlooked a major point in the IFT report and that is the role of history. If you just use pH and water activity, many traditional bread products would require temperature control. History has shown these traditional bread products are safe on the shelf.
- Much of this information does not pertain to how my organization functions. However, the information provided is thorough and straightforward. Nice work.
- Great work!
- ***The following Italicized comments are all from the same responder.*** *The 2005 Food Code does not sufficiently identify foods that are or are not TCS, nor does it provide a reasonable, practical solution for determining which foods should be classified as TCS or non-TCS. The Code includes charts that can be used for determining which foods might be TCS, but these charts are excerpted directly from the IFT report without the mechanisms in place for application. It is unrealistic to assume that states (and local) jurisdictions can apply the TCS definition and charts uniformly.*
- *The IFT report states, "The panel recognizes that the implementation of its approach in the field may not be an easy task. For example, although some of the considerations introduced in the proposed framework require careful evaluation and assessment by an expert microbiologist, this report does not attempt to propose who would be responsible for deciding the time/temperature status of a food."*
- *The new definition of PHF (TCS) should not be used until a protocol is established and a decision has been made as to who will be responsible for deciding the time/temperature status of food.*
- *Likewise, there is no guidance on the use of the charts by the industry. The IFT report states, "The panel also did not address the implications of the framework at the retail level." Can a retail store independently send a product to a lab (using AOAC methods) before an FDA approved protocol is available? What happens in the interim? If the pH and a_w meet the definition of a non-PHF/TCS, can the retailer keep the food out of temperature? Will regulatory authorities require documentation to be sent to them for prior approval?*
- *The IFT definition and application of TCS was designed for FDA use and could also be used by food processors/manufacturers. By incorporating it into the Food Code, it is assumed that all industries and regulatory bodies using the Food Code, including states, local jurisdictions and retailers will now be applying the definition and charts to many foods.*
- *By incorporating this definition into the Food Code, it leaves the states/locals in the position of having to decide how they will use the IFT framework, without offering the necessary scientific expertise and protocols the IFT says is needed.*
- *The Food Code is premature in incorporating TCS as the concept is only partially developed and it does not have an established protocol. The inevitable outcome will be inconsistent application and determination of TCS by regulatory bodies and the industry.*
- *The 2005 Food Code merely "cuts and pastes" part of the IFT report into the Code and Annex. Significant IFT information about handling, packaging and product history needed for the final TCS determination are not included in the Food Code. The IFT report needs to be adopted in total and not in part if it is to be effectively used.*
- *For example, the Food Code does not include the concept of product history. This is included in the Annex, although it is only listed as a question to consider in determining the status of a food as TCS. Unless a person applying the Food Code knows the history and scientific rationale for why a product like white bread is shelf stable, they must conclude it is TCS. As written, one would have to assume that under the 2005 Food Code, white bread is a TCS until other scientific information is presented.*
- *We agree that the term "potentially hazardous food" should be changed. It is not consumer friendly and may imply a lack of food safety rather than application of food safety controls. Foods that are "Temperature Controlled for Safety" sends the message that safety controls are in place, and it further serves to help consumers understand the importance of maintaining*

certain foods at proper temperature in the home. Therefore, we support the TCS term, but feel that the new definition is premature for general application.

- *Under the old PHF definition there has been inconsistent application and lack of agreement on "rapid and progressive growth" which has been interpreted subjectively.*
- *(Part 2) It is unclear who is expected to use the decision tree. It is too detailed for routine field application, and there is no guidance on who can make the final decision regarding the status of a food. Using the tree requires a significant amount of knowledge about the food, the production/processing methods, the food history, intrinsic and extrinsic factors, and the combination of these factors to make it a practical tool.*
- *Training for using the decision tree, along with training for use and application of all aspect of the TCS definition, needs to be standardized for all health departments and regulatory bodies using the Food Code. If industry (processors, retailers, etc.) will also be allowed to use the tree and determine the status of the food, they should also be included in the standardization training. Various methods can be used for training delivery as identified in the survey.*
- *Our recommendation is that the TCS definition and decision tree should not be used until the protocol and training are completed.*
- ***FDA's role:***
    - *FDA should take the lead in identifying PHF/TCS using the new definition. This would assure consistency and uniform application. Furthermore, it would save a considerable amount of time and money, and avoid conflicts over decisions about TCS. Many resources will be wasted by redundant testing of the same products, and resolving different results on the same product. FDA should first determine the status of most foods using the TCS definition and make this available. This can be done by FDA itself, by contract labs, or by companies who submit their own results to FDA for acceptance. Once this is established, then the TCS chart and decision tree can be used for other foods on a case by case basis.*
- The entire IFT document should be recognized and accepted. There is important information regarding the protocol to use for product assessment. There is also the section on "Product History and Traditional Use", which recognizes that there are foods that fall into the product assessment category that traditionally are not considered a PHF. These foods include fruits & vegetables (excluding cut melons and sprouts), bread, water, and some processed cheeses.
- Section (b) and the charts (A) & (B) should not have been included into the 2005 Food Code until an approved protocol and training are established.
- There needs to be a national (FDA) recognition of common food commodities that will be classified into the category of product assessment, but historically are not of public health concern. Having states and local regulatory authorities decide on these foods would not enhance uniformity and cause an undue burden on these agencies as well as industry.
- The protocol for evaluating prodcut assessments must be in place, training to that standard and a national review of common food commodities that have had a history of being safe must be in place prior to adoption of the (b) and Table A & B. It was premature to add this section into the 2005 Food Code without the foundation and training in place.
- PROTOCOL FOR THE VALIDATION OF CHALLENGE TESTING/INOCULATION STUDIES: IT SHOULD BE AN OUTSIDE TESTING ORGANIZATION THAT IS NOT DIRECTLY HIRED BY THE FOOD INDUSTRY, IT SHOULD BE AN ENTITY PAID FOR EVALUATION SERVICES BY HEALTH OFFICIALS FROM FEES OBTAINED FROM THE FOOD INDUSTRY REQUESTING THE EVALUATION
- When factors are used to alter food at the retail level there must be some level of control. One batch of the altered food may have a PA that indicates the food is non-PHF/non-TCS but if the same recipe and/or procedures are not used each time the result will not be consistent. Will a variance and or HACCP plan be required for all such products? If product history and scientific rationale is permitted to be used with no testing, foods such as sushi (rice) may be considered non-PHF/non-TCS although an inadequate change in pH has occurred to make it so. If the intended time of use/time at ambient temperature are taken into consideration when conducting a PA date/time marking of the food item should be required if it is a factor.

- The footnote addresses many of my concerns except that I know that validation is what is required. I believe protocols for reviewing/evaluating/interpreting data from these studies is more appropriate.
- I think that the transition to the term TCS is good and will benefit all. however, I predict that it will be met with much reluctance to accept its use in the field.
- While the definition may have scientific value, field staff DO NOT have immediate access to the instruments needed to determine whether a food falls within the ranges on the charts. How will the definition be useful during inspections?
- Annex is not law, so instructions must be in the code. As we make the code more difficult to understand and enforce, we need to ask whether our inspection work force is capable. I am not advocating "dumbing down" the codes, but it is like newer faster cars on old country roads- one cannot handle the other. This also imposes a fiscal burden on small programs and increases the time needed
- In the recommendations from the IFT report, if specifically states that "it does not specifically consider the implications of the recommendations for the retail store and food service industries". The food code is intended for use in regulating those industries. Why would the implications for those facilities not be considered? I think the charts are fine for use when someone is saying that this specific food is not a PHF/TCS food, but they are not practical for use in the field for determining if a food is PHF/TCS.
- I have concerns about the viability of sub-dividing foods based on various combinations of water activity levels and pH for the field inspector of retail food preparation and service facilities.
- Thank you for this needed step for improving the effectiveness of food safety training. Note - there may be some confusion as to the TCS status of pasteurized shell eggs. The packaging is labeled to keep refrigerated at 45 F. or below. (The proposed change states that pastuerized shell eggs are non-TCS?)
- Can you really trust the studies done by a manufacturer of their own product? Too many products are made these days only to be found harmful in a short time. Public Health should seek to avoid this pattern!!
- We would most likely require the vendor to supply proof that any food in qustions is potentially hazardous or not.
- I had heard a presentation at NEHA in June 2005 regarding this change in definition. That presentation along with the informaiton sent with this survey helped with my understanding of the topic. Thank you.
- A list of general foods with their pH and water activity values would help inspectors in the field (i.e. raw chicken, canned tuna fish, vegatables, etc.) Some foods won't nered to be thrown out if found at 50°F for over four hours if they now are considered to be a non-TCS Food.
- We would use the new definition to possible display items such as foccacia breads, etc. at room temperature using PA.
- Regarding PA – define expert microbiologist; how do we know what the vendor supplies is valid? Who is qualified to do a PA? What documents to support findings any consisting?
- How will a firm know the pH and water activity of a food item or combo?
- A definition that requires attachments, decision trees, etc. is probably not a good definition. If the inspector does not have the equipment to test pH or water activity of a product, then a determination cannot be accurately made.
- The manufacturer of the food product is legally liable for a food product they provide to the public. This present direction provides more discretion for manufacturers of food products to create/change a food product, provide it to the public and not require it to be held at proper temperatures and yet it may be a PHF.

ANNEX:

PART 1, QUESTION #1:

Follow-up Question 1a:

- Probably would be difficult to understand for an operator.
- I believe the acronym should be TTCS to acknowledge that BOTH time and temperature may be considered. I anticipate confusion on the part of field inspectors.
- The term is clear, the evaluation and lack of product assessment protocal is not clear.
- They should not combine the terms. I feel they should stay with just PHF instead of changing to TCS. Or if they are going to change, at least make it TTCS instead of TCS so either time or temperature is not forgotten.
- The definition is quite technical and quite confusing, especially with all of the water activity and pH charts and tables. With some training health inspectors will probably understand, however many food operators will be be quite confused.
- Industry and inspectors can relate. Operators and Food Handlers may have difficulty understanding.
- The PA /vendor documentation section needs some work. Perhaps more concise guidelines about what type of documentation would be appropriate or standard protocols for evaluating challenge testing data.
- So long and have a complex table
- Table A and Table B will be confusing to field staff and industry
- The term is OK, but the charts and actual wording of the definition is not easily understood.
- The new definition is not so much a "definition" as it is more of a concept. And since it's more conceptual, then it is subject to far more interpretation.
- I think it will be confusing to change the term with our diverse culture. I also don't like the word Food after the TCS. I would leave off the Food part or have it reworded to say Time/Temperature Control for Food Safety.
- In the second part of the sentence beginning with garlic-in-oil mixtures, I believe that the way that this sentence is currently written it is quite confusing. Maybe, if the sentence were reworded and without the "Not"….I think this would help.
- Too cumbersome to work with in the field
- The definetion is to long and insoectors needs a clear working definetion to apply in the field. They don't need charts and grafts.
- Not something that can be used in the field.
- Time/Temperature Control for Safety should be TTCS.
- The definition is very technical. I re-read it several times and finally understood its meaning after I read Attachment B. The diagram is very helpful (tree)
- Introduces so much scientific jargon that the averge operator will never understand. A 12 page FDA Backgrounder was almost too much for me to grasp.
- This depends on the person reading the definitions understanding, experience and education It may be difficult to understand for a food service operator.
- Just add to the current PHF definition – includes food that require Time/Temp control.
- Have to go to other parts (sub-paragraph (3) (d)) and use tables to make determinations.
- A regulatory person in the field should not have to determine it if a food product needs a PA.

PART 1, QUESTION #1:

Follow-up Question 1b:

- The “title” seems overwhelming – if we want to make it easy to explain to operators and consumers, it’s pretty technical.
- I believe the acronym should be TTCS to acknowledge that BOTH time and temperature may be considered. I anticipate confusion on the part of field inspectors.
- Clarification that there are certain non PHF's which would fall under a tcs classification that historically are not a public health concern.
- I don’t like the chart. I think they should be able to explain it in words.
- The pH and Aw values of common foods. A clearer understanding of PACKAGED. There has been some disagreement concerning securely wrapped.
- Training will have to be conducted on all aspects of the new definition. This is a significant change from the existing definition; in that, regulators will have to get into the habit of reviewing challenge testing and/or modeling results. I don't believe the average regualtor is in a position to do that at this point.
- The use of the tables would need to be addressed throught training and practice.
- PA- FDA should provide a list of products that require PA. Training on how to use TCS in the field will be needed. How to apply the tables in the field????
- The table should clearly and boldly state whether it is packaged or unpackaged (it is not BOLD), and directions for the tables should be in the code not just in the annex.
- Heat treated-in the food service establishment or in the manufacturing process? Are the charts only used for someone wanting to not hold food at proper temperatures? Are the charts to be used to determine if all foods are PHF/TCS? Is industry really going to follow through with product assessment? What if they don't? The charts do not simplify the definition, only further complicate the issue.
- Although the regulatory side will utilize this information, the decision tree is more appropriate for deciding whether to do product assessment or not.
- Validation of PA when CFSAN extablishes the protocol.
- The technology needed to make the determination is beyond what most inspectors can carry safely and are cost prohibitive for the department and the food service establishment
- The charts need to be made with examples of ones that need temperature controls and ones that don't
- If you want inspectors to use the definition at the field level make it more concise.
- If I have to use that definition I will have trouble - not a working definition for field inspectors.
- Product Assessment required - could you say “laboratory testing required” or is a TCS food?
- Product Assessment.
- Some scientific data might be easily understood by different levels of education.
- Time/Temperature Control for Safety should be TTCS.
- I would train on “Factors Influencing Microbial Growth” and concepts of p. xxvii of the IFT document.
- The use of tables for determination. The use of attachments for determination.
- Who is responsible for what?

PART 1, QUESTION #2:

Follow-up Question 2a:

- I just don't think time/temperature control for safety is meaningful for the average person handling food. Is there some generic label like requires special care (handling) that could denote those foods requiring time/temperature controls? Or high risk?
- Time and temperature are the elements that must be controlled for these foods. People frequently get confused because that many foods could literally be potentially hazardous if contaminated with a pathogen, but would not fall within the definition of the Food Code.
- Because it will take 10 years plus for this definition to become part of the regulatory lexicon and it allows for a transitional term to help the field person apply it properly.
- PHF is easier to remember. Too many acronyms is confusing.
- I think it would be easier to replace PHF if this was gradual. This will give a period of time for training and association of the new term TCS with the old term PHF.
- Easier to explain to others.
- There are Potentially Hazardous Foods that are not TCS and for the purpose of the subject there needs to be a separation.
- Clearer that temperature control is significant in limiting growth.
- TCS is easier and more simple for consumers to grasp and understand. PHF gives consumers the impression that the food should be avoided.
- Ease of transition for training Opertors
- The use of both terms interchangeably will be confusing to our operators. It would be better to change to the new term as I believe that operators will learn it quickly and all of us can be on the same page when using the term.
- TCS is very easy to understand. No need to delay transition
- I think it is easier for the industry and the public to understand. It places emphasis on the safety of the food. Potentially hazardous sounds too ominous and the term is misunderstood.
- The lesser of two evils. Both terms will be extremely confusing to most food operators, TCS has a better chance of being comprehended.
- Help with transition.
- I always explained that a PHF was a food that required refrigeration.
- It needs to be phased out for clarity purposes with the public.
- This gets people thinking about the new concept sooner
- It is short and easy to understand
- I have encountered confusion and, in one case, alarm because of the term "Potentially Hazardous Food". This was expressed by a state legislator who was very concerned about the implications of the use of the term "hazardous".
- Prefer that the change be made AFTER proper training
- The first choice is redundant- TCS more accurately describes what safeguards are needed.
- Familiarity with PHF term.
- The term is self explanatory on how the food product is to be handled
- I always thought that "potentially hazardous foods" was too negative sounding
- It explains exactly what the food needs to minimize bacteria presence - time and temperature control.
- Having one term simplifies translation of the code language to our customers
- BECAUSE PEOPLE WILL UNDERSTAND THAT PHF WILL NEED TCS
- Give persons time to become familiar with new defintion.
- PHF-when used in the field gets peoples attention. Currently used to explain what PHF is and how it relates to elements of the standards set. Combined with TCS, I feel gives a better understanding.
- All foods could be considered potentially hazardous, wether it be by temperature abuse, cross contamination, etc. The TCS is a more precise definition of what we are looking for.

- PHF is more simple to understand and use
- Will the PHF differ from what they are now?
- Most inspectors don't know what TCS means – at least with PHF they have a clue.
- Time/Temperature or just Temperature? Foods can be potentially hazardous but not need temperature control for safety.
- I would just make a note the PHF is replaced with TCS.
- Make change now and avoid phase-out which will only delay understanding.
- Again, this depends on your knowledge lever, but I think TCS spelled out may make better sense. I think it is also important to get the time in the definition, not just the temperature aspect.
- Potentially hazardous food sounds like more of a chance something could go wrong with the product. Calls out the word hazard.
- Familiarity with the old term.
- Until people get used to new terminology – also change to TTCS.
- Easier to understand – little confusion.
- I prefer the broader scope given to "PHF/TCS".
- Would rather see just PHF.
- PHF is universally understood – it heightens food safety awareness.
- Some manufacturers put "Keep Refrigerated" on their containers of food even though the food is not a PHF.

PART 1, QUESTION #3:

Follow-up Question 3a:

- The current definition requires refrigeration of products that do not support rapid and progressive growth of pathogens.
- I almost answered no, because the problems stem from an inspector not knowing, for example, that a sauce is commercially prepared and thus non-phf. I don't think that's a problem with the definition but a problem with the inspector's understanding of it.
- Very little uniformity in determining rapid and progressive growth
- Only because more and more foods fit the definition of TCS; that under the old PHF definition created confusion.
- Some people "just don't get it". Also, just what is hazardous? And it takes needles time to explain. and the next thing you have is a different person.
- Many of our food operations do not understand the term PHF when used. As this term is explained to them, they have appeared to have comprehended only to find at later inspections that they have forgotten or have not grasped the gist of the term. Again, with the problems we have experienced with the PHF term, TCS will not be much better. It would be more practical to use more lay-mans style terms such as "hazardous foods" or "foods requiring controls" to explain PHFs for most common food operators.
- Complication with the operator's knowledge of food and education level.
- Some language and intelligence barriers.
- The current definition does not address slow growing pathogens such as Listeria. Also, several pathogens can grow at pH < 4.6., example; Listeria 4.4; Salmonella 4.2; and Yersinia 4.2. Only Staph has been shown to grow at aw of .88; therefore, setting aw limit at 0.85 was perhaps too restrictive.
- Some of the same confusion indicated in previous question - the term PHF carries with it implications that are not readily understood.
- Generally, no
- No ability to use aW and pH together without use of laboratory results.
- Because of the factors that the two new tables spell out (i.e. lack of water activity meter and pH meter in-field).
- WE HAVE NOT IMPLEMENTED IT YET
- it's been a matter of keeping up with food technology rather than changing the definition
- Sometimes we are unsure whether foods are potentially hazardous or not.
- Some inspectors don't even know PHF definition and use manufacturer's labels "Keep refrigerated" as the designation for a PHF.
- Pies, dressings, sauces, items made from scratch – combo of ingredients that may alter a PHF to a no –PHF or vice versa.
- I believe that ice cream is a PHF.

PART 2, QUESTION #1:

Follow-up Question 1a:

- Both Yes and No answers to question 4 lead to the same action. If it is packaged to prevent contamination after heating, the arrow should point to Table A. No should point to Table B.
- Without a protocol to evaluate food the the category of prodcut assessment, chart cannot be used. Needs to be a national acceptance body (FDA) to evaluate groups of common food items that are not easily identified using the chart matrix.
- At times it is difficult to follow.
- Mostly because it is a new approach that is going to get some getting use to.
- How do we determine pH and aw values in the field?
- Chart is too busy. What if the know pH and aw values are not known in the field? Is there a chart available with all known pH and aw values?
- Question 6 asking to use appropriate table . This should be a decision question to lead to Table A or B. The question was asked earlier in #2 so if you said No then #6 under question #3 should lead you to table B. Not a determination on whether it is A or B
- C'mon, let's be real here. Leave the scientific crap in the lab where it belongs, not out in the field with the inspectors.
- a five page decision tree is not easy to use or understand
- I don't know what the tree is.
- Not a field useable tool.
- I have not seen decision trees with a “maybe” selection.
- It is manufacturer’s responsibility to make a determination whether his food product is a PHF and must be kept at proper temperature.

PART 2, QUESTION #2:

Follow-up Question 2a:

- Both Yes and No answers to question 4 lead to the same action. If it is packaged to prevent contamination after heating, the arrow should point to Table A. No should point to Table B.
- Need to include the entire IFT document, Evaluation and Definition of PHF
- The decision tree is easy to use; however, I don't believe the intent of the operator is as important as how the food is actually being held. Many operators intend to keep the food out of the danger zone by implementing SOPs but many food service workers only adhere to the SOPs during periods that are not busy.
- There will be questions in the field regarding product pH and/or water activity in order to use the Decision Tree.
- Though the tree is understandable, it is not very easy to use. I think that the practicality of the decision tree might also be questioned, especially by regulatory staff in the field.
- Cumbersome and confusing for field application
- withholding judgement at this time- not sure how complex this may get in a large facility
- Chart is too busy. What if the know pH and aw values are not known in the field? Is there a chart available with all known pH and aw values?
- Too much time and instrumentation might/will be necessary for practical field application
- I don't think that it's practical or easy to use since it references several documents that are not included in the chart-A/B easily. Also, in question 4, both yes/no arrows go to the same box--why is this even important then?
- C'mon, let's be real here. Leave the scientific crap in the lab where it belongs, not out in the field with the inspectors.
- a five page decision tree is not easy to use or understand
- To use it you need to know the pH of everything.
- Water activity meters and pH meters introduce concepts most operators are ignorant of.
- If pH or water activity is unknown, then what?
- It is manufacturer’s responsibility to make a determination whether his food product is a PHF and must be kept at proper temperature.

PART 2, QUESTION #3:

Follow-up Question 3a:

- There are more variables and might be too technical for some to comprehend.
- I THINK THEY SHOULD TRY AND KEEP IT SIMPLE. ON THE LOCAL HEALTH DEPARTMENT LEVEL, IT IS NOT LIKELY THAT WE ARE GOING TO BE ANALYZING DATA SUBMITTED FROM TESTING AGENCIES TO DETERMINE THE PH AND WATER ACTIVITY OF FOODS.
- The majority of our staff are either veteran inspectors that have been around for a decade or more or new comers who have been with us for two years or less. In either case change is somewhat difficult. The veterans have their own ideas and quirks and are sometimes resistant to change - especially when the change is not cut and dry. The newcomers have just recently completed all of their training including learning all the laws and rules. They have experienced minimal change thus far and are only beginning to have confidence in their own judgment.
- Problems will be encountered in the PA category. Field staff will need training in evaluating challenge test results and/or information provided by manufacturer. Process of evaluating these materials will require a solid background in microbiology.
- Some of our staff members have been in the field for years and to make any changes will be met with difficulty. This is not to suggest that the concept of the TCS foods will be difficult, but rather the implementation of the changes into the day-to-day practices of the field staff.
- The decision tree is not too hard to understand. The problem will be industry who will be asking "who is to determine the ph and water activity" Many of the products may be TCS food on one inspection but not on the next. Enough thought the science is there to support this method, it will be difficult to manage in the field.
- The new system adds complexity to determining when TCS is needed. All inspectors need new equipment that must be maintained and calibrated.
- Chart is too busy. What if the know pH and aw values are not known in the field? Is there a chart available with all known pH and aw values?
- Change is always hard
- Too much time and instrumentation might/will be necessary for practical field application
- I FIRST HAD TO TRANSLATE IT IN SPANISH AND THEN GIVE TRAINING TO OUR INSPECTORS ABOUT IT.
- The staff are inspectors that uphold the Public Health Code as it is written. We are not microbiologists who are in the field to determine the scientific data.
- If they have kept up with changes in food technology, the change will be moderatly difficult. IF not, it will be a nightmare. Explaining this to managers could take all day also.
- I do not know all the properties of the different foods.
- The information is too technical. Field inspectiors are not going to use in the present form.
- The tests are lab oriented.
- Do not currently take pH and water activity measurements in the field.
- Will we need to test foods ewith pH and water activity meters before writing critical violations for food out of temperature? This will be the difficult part.
- Meters unavailable, costs high in time of limited budgets, constant calibration issues certain to arise.
- Scientific language used, education levels of field staff will have an influence on understanding.
- Any change, especially one as complex as this will be difficult. State varies on education, experience, etc., which is a factor – different people learn at diverse ratios.
- Based on experience with NACMCF, Decision tree for CCPs, this is even more involved. Will require a culture change in some of inspection staff for implementation.
- If pH or water activity is unknown, then what?
- It is not regulators responsibility in field to do analysis of food products to determine water activity, pH etc. to determine PHF.

PART 2, QUESTION #4:

Follow-up Question 4a:

- Workshops
- Online
- Online would be great and accessible to many.
- Online
- Any of the above would be beneficial.
- Online
- Online
- WORKSHOPS, PRESENTATIONS, HANDS-ON.
- PRESENTATIONS GIVEN THROUGH OEHA, ODH, OR OTHER REGIONAL FOOD ORGANIZATIONS
- Video conferences
- Workshops or Presentations involving real people. Its makes asking questions a little simpler.
- None for local staff
- Online training would be a great benefit because of the geographical spread of our inspectors. Presentations are the next best thing so inspectors can ask questions and don't feel quite so intimidated as at a conference.
- A mixture of field and online workshops would be most beneficial.
- All of the above
- Online/workshops
- Workshops
- Workshops, conferences
- Online, presentations at health professional meetings, conferences, etc.
- Workshops
- Workshops in Spanish, because not all the Inspectors speak English
- Workshops, presentations
- Online workshops or video
- Online, workshops
- Workshops
- hands-on workshops and presentations
- Workshops and face to face presentations.
- Presentation that could be used in house to staff.
- on-line, video conferencing
- Workshops
- There should be some online training program (i.e. computer self-study) which presents information, asks standardized questions, and then produces a certificate of completion at the end. This will measure whether or not the information was understood or processed.
- PRESENTATIONS & WORKSHOPS
- All of the above
- work shops similar to field situations
- None
- all since people learn differently and reinforcement is necessary via alternate methods
- all of the above
- All of the above. The style of training will depend on the person and the type of information they are trying to collect.
- Workshops – hand-on training, tell me, show me, let me do it.
- Workshops where questions can be asked and answered.
- All of the above.

- This needs to be trainable and enforceable. Inspectors and operators will need to be able to understand and enforce it. Most oerators are not reading the Food Code but getting their training through a ServSafe or similar program.
- Online.
- Online.
- Online and presentations.
- Workshop
- Workshops, presentations, online.
- Workshops, presentations, hands-on working models.
- Workshop or video conference.
- Presentations from the (individuals) that adopt this definition and expect regulatory people to make this determination in the field.

PART 2, QUESTION #5:

Follow-up Question 5b:

- 3-4 years
- 6 months
- 2-3 years
- Unsure
- Whenever adopted by the state.
- Unsure
- With the change in the rule and some training, I would expect that this could easily be accomplished within 12 months.
- We would go with the whole State - process could take a bit… perhaps 6 - 9 months
- A few years. We just adopted the 2001 FC.
- 1 year
- Decisions made at state level
- Unsure
- 1 year
- Unsure
- As soon as it is adopted, it could be incorporated.
- Next food code revision (2-3 years)
- 6 months to one year. We adopted by reference the most recent version of the Food Code. When the code change, also we change.
- unsure, but if the change were incorporated, possibly 5 years.
- Unsure
- At least 2 years
- 6 months
- 3-4 years
- Working on adoption of 2005 code currently.
- This Fall 2005 we are planning to adopt the FDA 2005 Food Code
- 1 year
- 2 years (based on procedures/politics in state)
- 6 months
- SIX MONTHS FOR TRANSLATION AND TRAINING
- Up to management
- Unknown
- Not less than 1 year
- Years
- Depends if state adopts it
- 9-12 months if we considered it.
- Years.
- Unsure - adoption and rule making by the state and then creation and adoption of county ordinance.
- Depends on the state.
- Years; took a decade to adopt the last code, i.e., when 1993 code debuted we initiated effort, finally adopted 2001 version in 2004.
- 1 year.
- 18 – 26 months.
- 6 months.
- 1 – 2 years.
- If a part of the 2005 Food Code should be a moderately extensive project.
- 5 – 10 years – depends on state adoption process.
- 3 years after in federal code.

2004 - 2006 Conference for Food Protection
Council I
TCS (Temperature Control for Safety) Food Implementation Committee Final Report

In 2004, Council I of the Conference for Food Protection created the Potentially Hazardous Foods (PHF) Committee. The amended charge indicated a two-part responsibility regarding this committee as detailed in the issues below:

Issue No. 2004 I-012
Title: Revising the definition of "Potentially Hazardous Food" in the Food Code.

Recommended Solution:

The Conference recommends that based on discussion and deliberation,

(A) FDA revise the definition of "Potentially Hazardous Food" in subparagraph 1-201.10 (B)(65) of the 2001 Food Code in the following way:

1-201.10 (B)(65) **Potentially Hazardous Food.**

(a) **"Potentially hazardous food"** means a FOOD that requires time and/or temperature control for safety (TCS) to limit pathogen growth or toxin formation."

(b) **"Potentially hazardous food"** includes:

(i) An animal FOOD (a FOOD of animal origin), including fresh shell EGGS, that is raw or heat-treated; a FOOD of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(ii) A FOOD whose pH/a_W interaction is designated as TCS in one of the tables listed in paragraph (d).

(c) ***"Potentially hazardous food"*** *does not include:*

(i) An air-cooled hard-boiled EGG *with shell intact, or a shell* EGG *that is not hard-boiled, but has been treated to destroy all viable* ***Salmonellae****;*

(ii) A FOOD whose pH/a_w interaction is designated as non-TCS in one of the tables listed in paragraph (d);

(iii) A FOOD*, in an unopened* HERMETICALLY SEALED CONTAINER*, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;*

(iv) A FOOD *for which laboratory evidence demonstrates that time and temperature control for safety is not required, and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or*

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

(d) **Potentially hazardous food"** does not include food that, because of pH, water activity (a_w) or the interaction of pH and a_w, is considered non-PHF/non-TCS in Table A or B below.

Table A. Control of spores: Product heat-treated to control vegetative cells and 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	PA
> 0.95	non-PHF/non-TCS	PA	PA

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	PA
> 0.90 – 0.92	non-PHF/non-TCS	non-PHF/non-TCS	PA	PA
> 0.92	non-PHF/non-TCS	PA	PA	PA

PA = Product Assessment Required

(B) And that a PHF Committee be named to work with the FDA on this issue, charged to consider the best implementation strategy for state/local regulations and the food service/food store industry to determine whether a food is PHF or not, based on the IFT Report, to determine whether the term PHF or TCS is preferred and to report back to the Conference for Food Protection Executive Board by the 2004 Fall Board Meeting.

1. **Issue No. 2004 I-012 Part (A)**
   The TCS Food Implementation Committee ("TCS Committee") reached consensus on a portion of the committee charge for the preferred term PHF vs. TCS during the first conference call on July 22, 2004. The TCS Committee chose TCS (Temperature Control for Safety). The TCS Committee believes that this acronym provides more clarity and information than the term "potentially hazardous" food, while providing additional information on the "why/how" the products are to be handled for safety. The term TCS also helps eliminate confusion in terminology with the word "hazard" used in HACCP programs.

2. **Issue No. 2004 I-012 Part (B)**
   The TCS Committee kept to a monthly conference call schedule to complete part of the committee charge in the development of a document to assist in the determination if a food is TCS food. The document is a decision tree and was submitted to the FDA on December 1, 2004 to meet their writing committee deadline, was accepted and incorporated into Annex 3 of the 2005 FDA Model Food Code.

   The committee conducted a survey that was sent to various regulatory jurisdictions, industry trade groups, CFP list serve, etc. to obtain general feedback on expected training needs, clarity of the decision tree and its practicality and ease of use, etc. The survey provided useful information to the committee and is the basis for three (3) of the committee's issues to be submitted. *(See Attachments for the complete survey.)*

   The committee also completed an expanded and more detailed guidance document designed to provide more information for using the new TCS food definition which includes several examples of how to determine if a food is TCS using the Decision Tree found in Annex 3 of the 2005 FDA Model Food Code.

   The survey was instrumental in identifying questions and issues concerning the implementation of the revised definition and provided the basis for a set of "Frequently Asked Questions" (FAQs) being developed by FDA. The committee will continue to act as stakeholders and provide input into the FAQs before they are put up on FDA's website.

3. The TCS Committee will submit four (4) issues at the 2006 Conference based on the survey results as well as other needs identified by the committee. The issues are:
   - Change "TCS Food" to "TTCS Food",
   - Request the FDA take a position on recognized/acceptable product assessment methodologies,
   - Request that the TCS Food Implementation Committee's report be acknowledged, and
   - Request that the TCS Food Implementation Committee be continued and in conjunction with the FDA and ORAU, develop a model training program to meet

the needs of regulatory and industry in the transition, application and implementation from PHF to TTCS food and to respond to all questions in the committee survey.

4. The TCS Committee has successfully completed charges from the Council I Chair and the CFP Executive Board for the last two (2) years. The TCS Committee respectfully requests that the Council Chair/CFP continue the committee, as there are additional charges the committee wishes to address as outlined in an issue submitted by the TCS Committee.

Respectfully Submitted By:

2004-2006 Council I TCS (Temperature Control for Safety) Food Implementation Committee Members
Darlene McDonnell – Vice-Chair
Pam H. Williams – Chair

Attachments *Committee Member Roster*
Survey
Guidance Document

HOW TO DETERMINE IF A FOOD IS A TCS FOOD

INTRODUCTION

The 2005 FDA Food Code definition of potentially hazardous food (PHF) was 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 and does not require time/temperature control for safety. The Food Code, in Section 3-501.19 Time as a Public Health Control, also provides safety parameters to use when time alone (without temperature control) can be used.

In 2004, a CFP committee was formed to work with the FDA 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). 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 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 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 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.

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 non-PHF (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-PHF (non-TCS Food) because of its pH or water activity alone or 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 was 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. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

a_w Values	pH Values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	Non-PHF*/non-TCS food**	Non-PHF/non-TCS food	Non-PHF/non-TCS food
> 0.92 – 0.95	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 means "Time/Temperature Control for Safety 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 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 § 3-401.11 of the Food Code (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 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. 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 Values**			
	< 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"**
**** TCS means "Time/Temperature Control for Safety Food"**
***** PA means "Product Assessment Required"**

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 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-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:

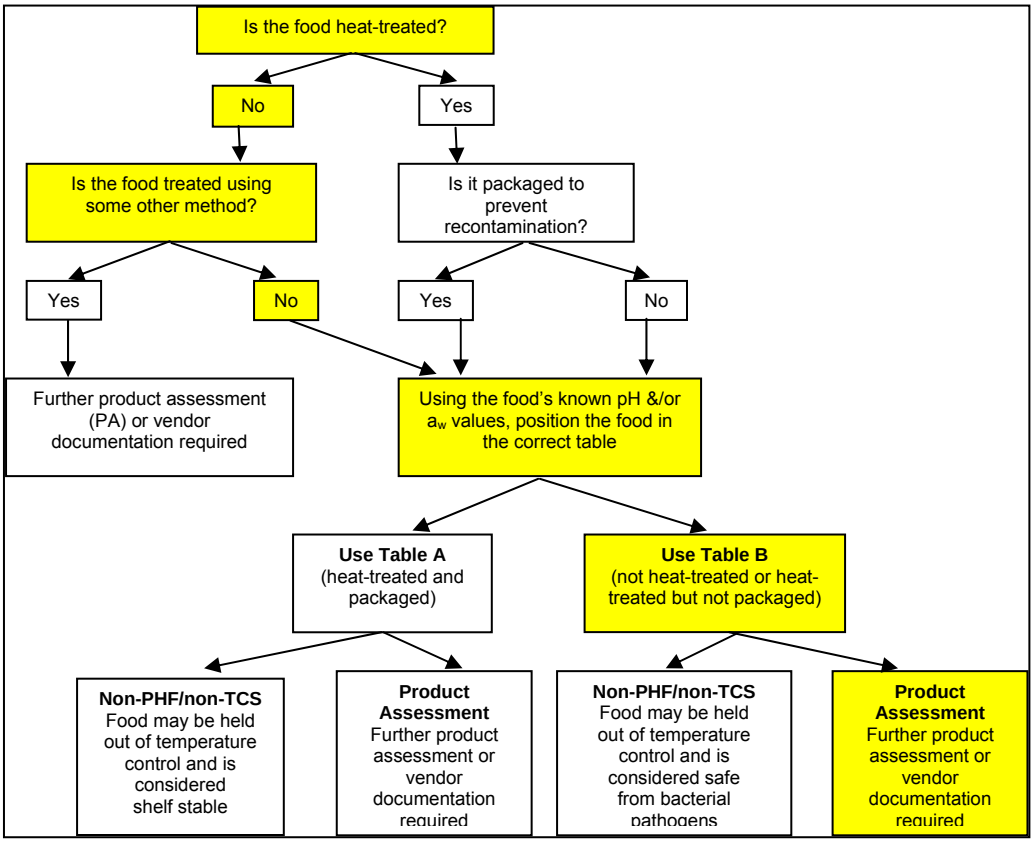
Cut melons are an example of fruits that are considered potentially hazardous once the outer rind has been penetrated. Infiltration studies have shown that pathogens are able to enter the stem end of cantaloupes, as well as through bruises and cankers. This is especially true when water containing the 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 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 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)



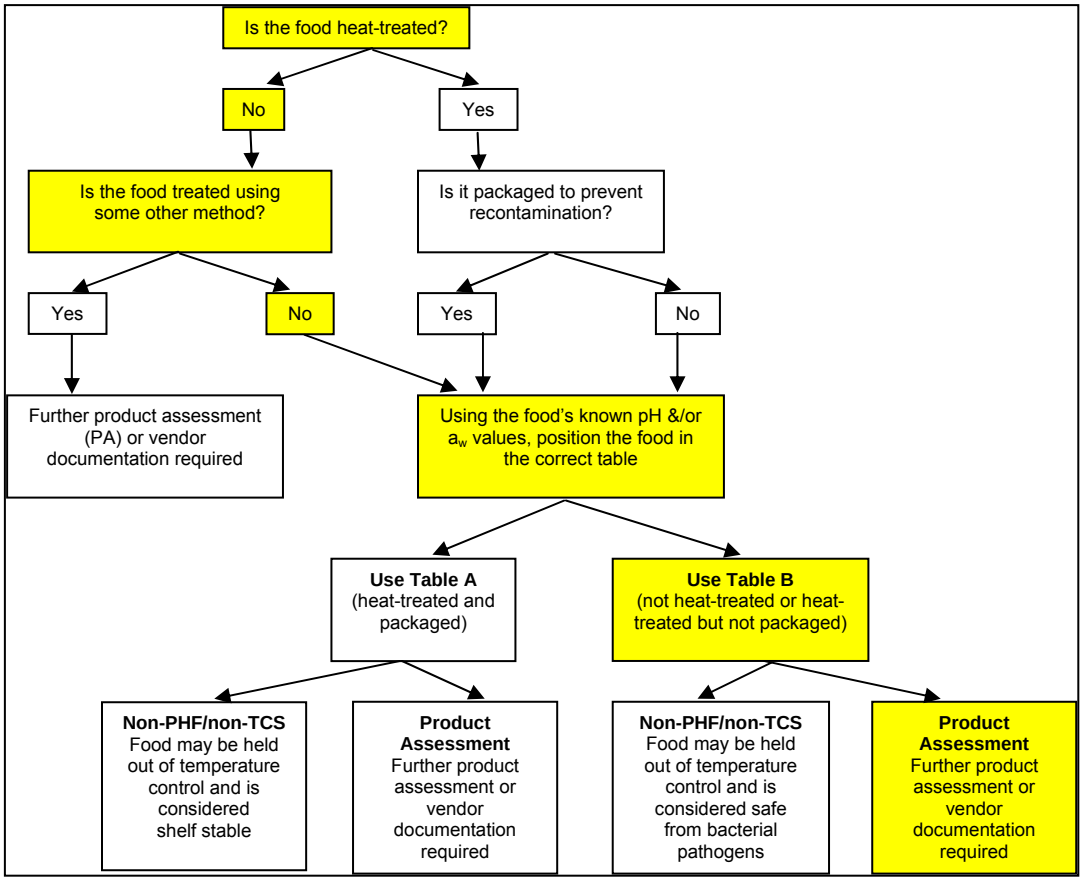
Raw Seed Sprouts:

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)



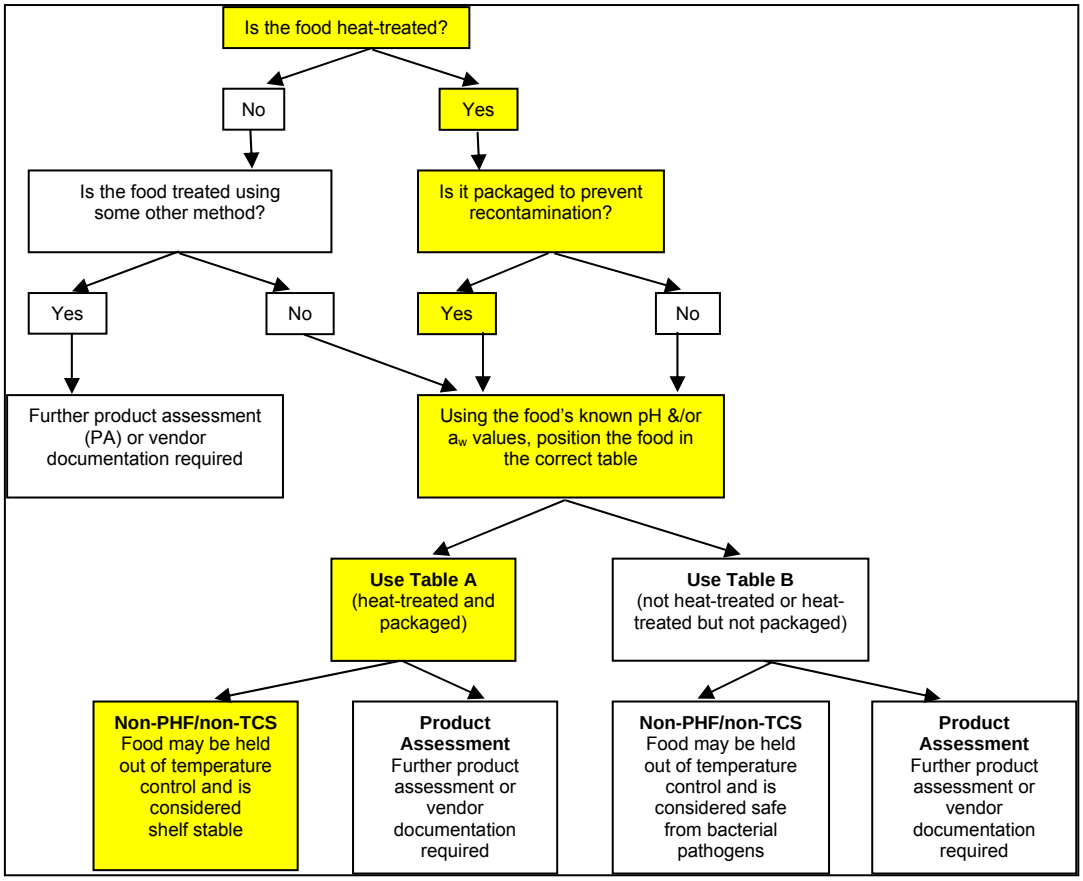
Parmesan Cheese:

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 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)

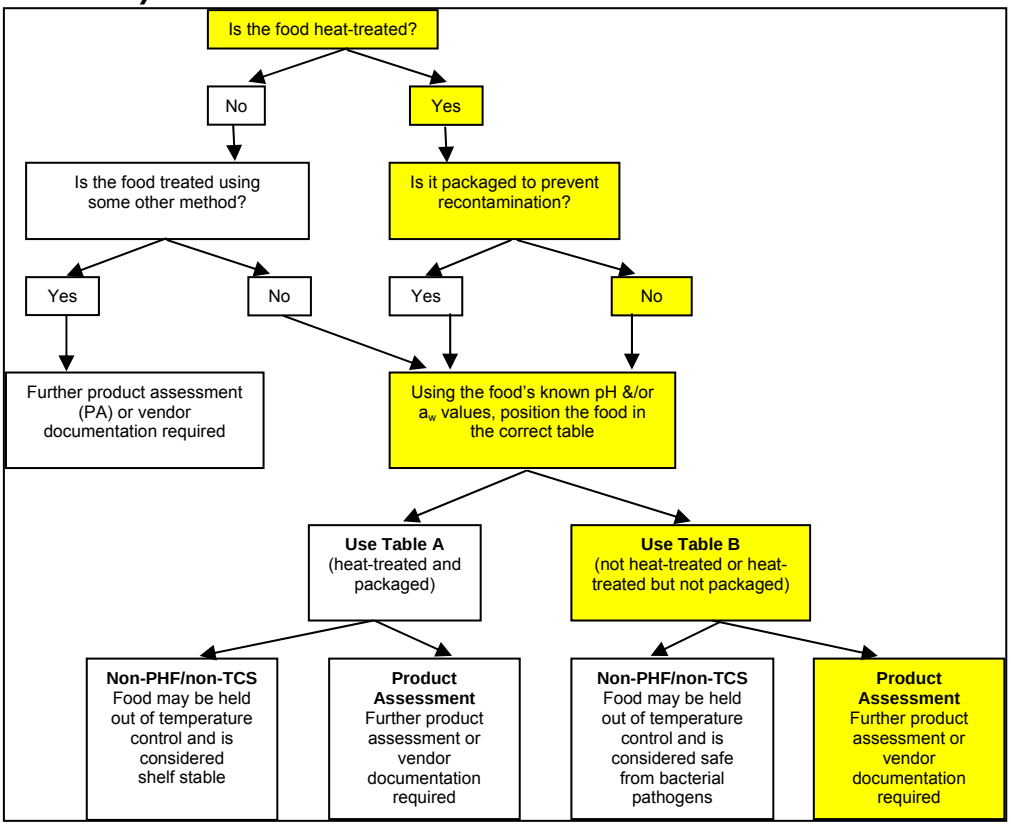


American Processed Cheese Slices:

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 placed atop 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 its American processed cheese slices at room temperature for a limited period of time because the refrigerated cheese slices cool down 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 testing 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.

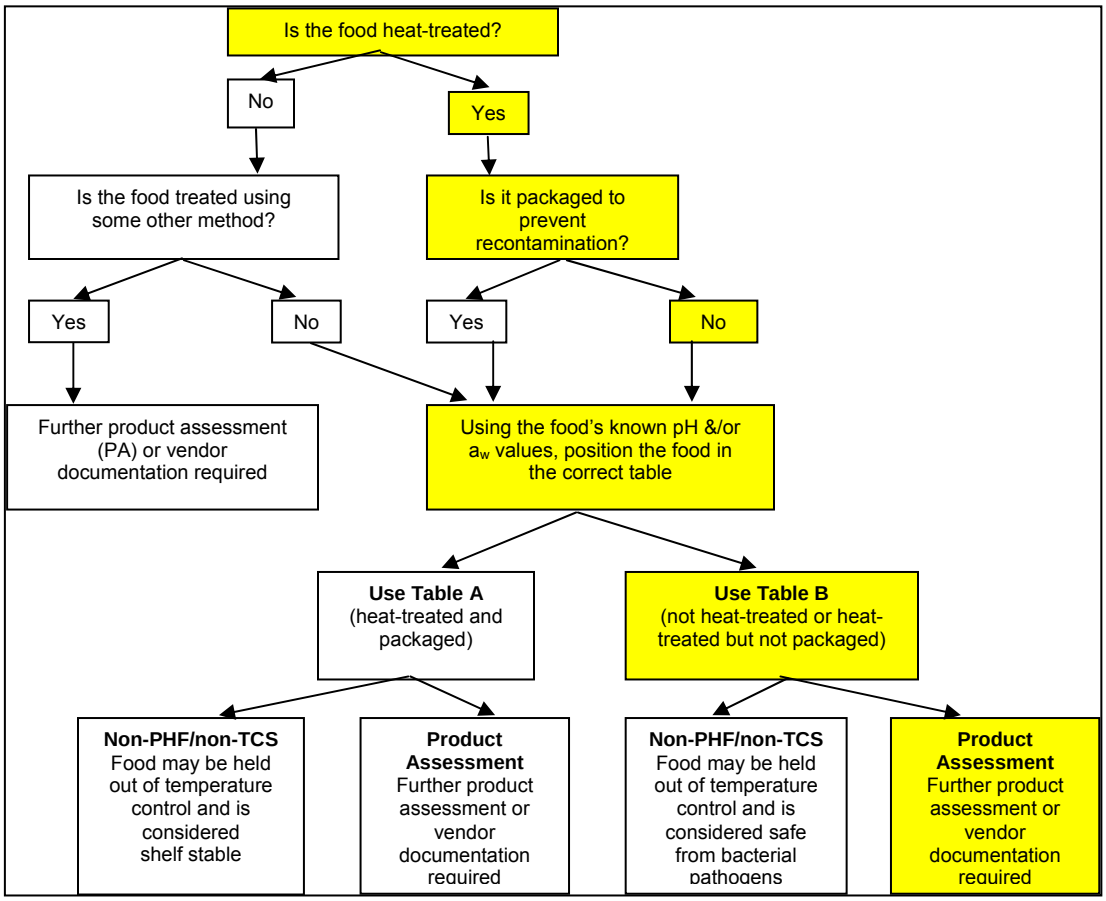
Although the cheese slices are not considered Non-PHF (Non-TCS Food), they may be safely held out of temperature control for 24 hrs. provided the ambient temperature does not go above 86° F and provided the cheese used is from one of the two suppliers used in the inoculation study.

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) of 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)

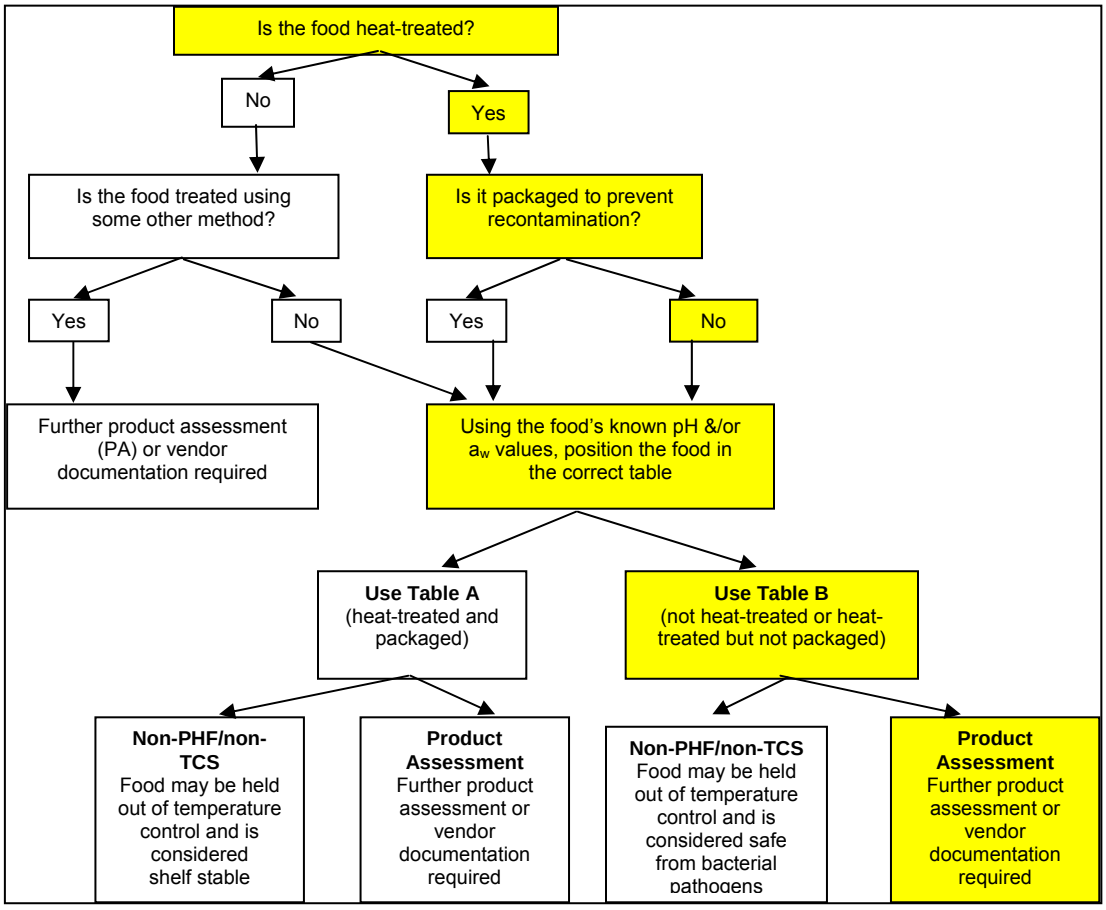


Sushi Rice:

Sushi rolls with raw fish 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-PHF.

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 a_w. 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 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 is a PHF (TCS Food)

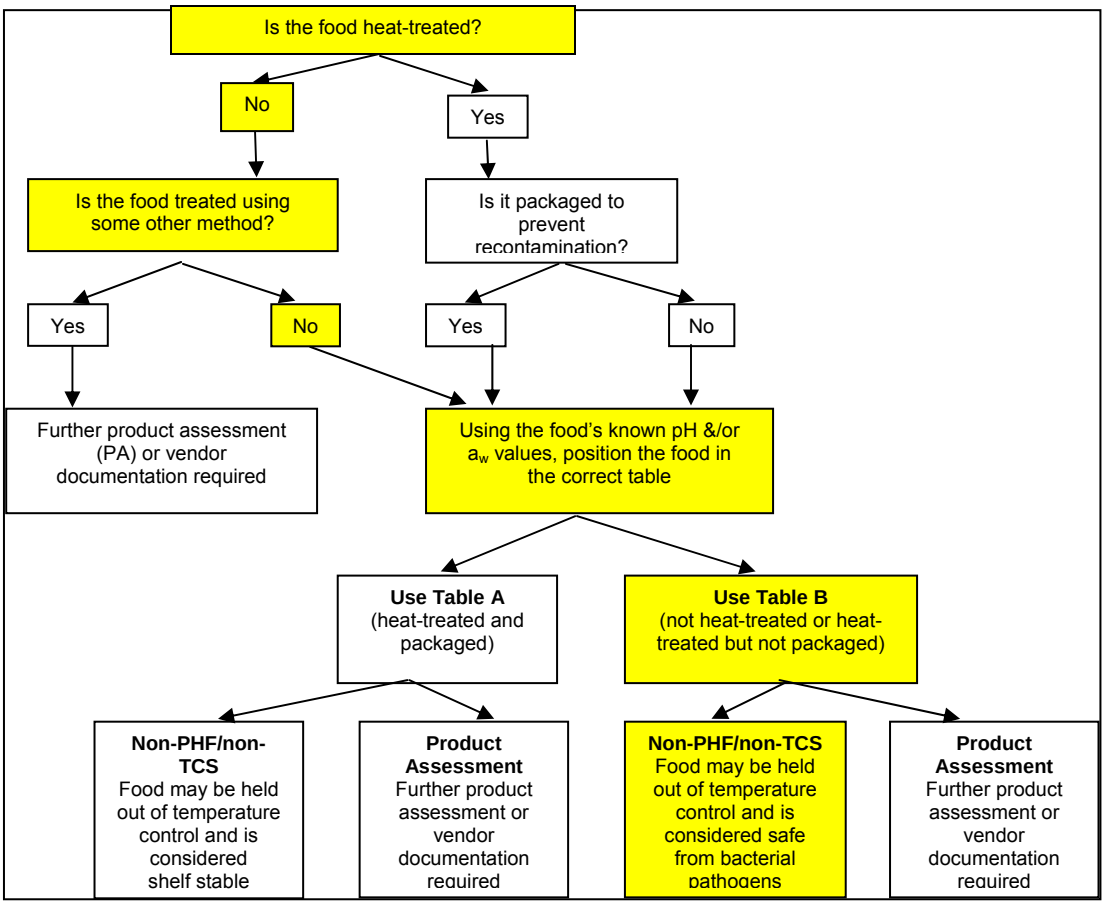


Salad Dressing/Sauce:

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 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 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-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 without temperature control.