Conference for Food Protection
2018 Issue Form

Issue: 2018 III-019

Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014 III-005 and 2014 III-006; the recommended solution has been revised.

Title:

Amend Food Code - Room Temp Non-TCS Food Becoming TCS, Then Held Using TPHC

Issue you would like the Conference to consider:

Amend section 3-501.19, Time as a Public Health Control (TPHC) of the FDA Food Code to allow for non-TCS food at or below 70°F to be held using time without temperature as the public health control from the time that product becomes a TCS food.

Public Health Significance:

When using TPHC, in 3-501.19 (B) (1) it is required to have the FOOD at an initial temperature of 41°F or below prior to being removed from temperature control. Following this criteria, a TCS food may then be left out of temperature control when utilizing time as a public health control for up to four (4) hours.

3-501.19 TPHC does not allow for a non-TCS food at ambient temperature, at the time that it is made into a TCS food (e.g. the act of cutting a whole melon, a whole tomato, harvest cut leafy greens; or opening canned tuna/chicken and making it into a sandwich spread; or mixing pancake/waffle batter that is prepared from ambient temperature ingredients) to be time stamped, left out for four (4) hours during service and then discarded, cooked and served, or served before the time limit is exceeded.

Non-TCS foods that are made into TCS foods must first be cooled 41°F or heated to or 135°F before an operator can utilize 3-501.19 TPHC. Therefore freshly mixed pancake/waffle batter at ambient temperature must first be chilled to or below 41°F before it can be time stamped and time as a public health control parameters in the code can be utilized. Under the Cooling section, 3-501.14 (B) allows for TCS foods that are made from ingredients at ambient temperature, up to four (4) hours to remain above 41°F. This TCS food can then be maintained at or below 41°F for up to 7 days prior to being removed from temperature control using TPHC under 3-501.19 for up to another four (4) hours (or even six (6) if maintained below 70°F).

In the FDA Food Code Annex section 3-501.19 it states:

"For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of L. monocytogenes remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for L. monocytogenes in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow L. monocytogenes growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, L. monocytogenes would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly."

The above studies show LM growth is less than 1 log at 68°F-70°F in egg and milk products and in the PMP model under optimum conditions at 75°F for up to 4 hours showed a slow rate of LM growth.

As LM is not specific to any particular TCS food and the food code currently allows foods from ambient to be out of temperature control for up to four (4) hours, therefore, a non-TCS food that becomes TCS to be kept for 4 hours will still allow an adequate margin of safety.

To substantiate the information in Chapter 3 of the Annex and provide greater detail on specific TCS food items, the 2012 TPHC CFP committee provided a report and submitted two issues. In 2014 based on the recommendations of the 2012 TPHC committee, CFP passed issues 2014 III-005 and 2014 III-006. Both of these issues were very similar to this issue. The FDA's response later that year did not concur with the recommendations of the CFP to adopt the recommended changes of the committee due to a couple of elements. In their response letter the FDA indicated concerns over identifying a single maximum temperature and if it is necessary to provide an itemized list of foods to which this criteria would be applied. No updates as requested by the 2014 biennial meeting to 3-501.19 have been made.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Section 3-501.19 of the most current FDA Food Code be amended as follows (language to be added is underlined):

Section 3-501.19

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control<u>, or at which time the FOOD is made TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and shall begin below 70°F</u>; [P]

(2) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control<u> or at which time it becomes a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD</u>; [Pf]

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Supporting Attachments:

- "2012 TPHC Committee Final Report"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: Time as a Public Health Control

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council III

DATE OF REPORT: December 6, 2013 (revised February 16, 2014)

SUBMITTED BY: Sue Vergne and Charles Otto on behalf of Committee Members

COMMITTEE CHARGE(s):

Issue # 2012 III-026

The Conference recommends:

That a committee be formed to identify safe times at which foods can be held without temperature control and without cooling to 41°F, supported by scientific information (e.g., challenge studies, modeling tools).

The Committee's charge shall include, but not be limited to, the following foods and food categories:

- Cut tomatoes
- Cut cantaloupe
- Chopped leafy greens
- Chopped garlic and oil
- Opened canned tuna
- Opened canned beans (e.g., green beans, chickpeas, black beans)
- Hummus
- Opened canned product used as a sole item
- Opened canned product used as an ingredient in a formulation

The committee may wish to consider a document published by Institute of Food Technologists (IFT) in 2001 and a National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) challenge study document. The Committee is also charged to report recommendations back to the 2014 CFP biennial meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

a. Summary:

The Time as a Public Health Control (TPHC) committee chairs were selected by Council III Chair and Co-Chair. The committee members were recommended by the committee chairs from a list of interested conference members with an emphasis on balance of constituencies and experience with the conference. The attached roster contains the individual's confirmed by the Board.

The committee held its first meeting a month after the membership roster had been accepted. The committee used a web conferencing format for its twelve meetings. With the permission of the members in attendance, the meeting proceedings were recorded and the link was provided to all members for review. This recording and the detailed committee minutes assisted the members who had missed a meeting the opportunity to stay current with the committee's deliberations.

The committee initially reviewed both 2012 Council recommended documents, IFT's Evaluation and Definition of Potentially Hazardous Foods (2001), and NACMF Parameters for Inoculated Pack/Challenge Studies (2009). The 2004-III-0009 Issue passed and submitted to FDA following the 2004 CFP biennial meeting (to establish the current Food Code requirements first published in the 2005 edition) was also consulted. The committee members also familiarized themselves with the two leading pathogen growth modeling programs, the USDA Pathogen Modeling Program (v.7) and ComBase.

The committee examined each of the nine foods and food categories in turn during the web meetings. Committee teams reviewed the literature on foodborne outbreak risks and associated pathogens of each food and food category.

The basic growth parameters of pH and A_W were also considered. The committee also deliberated on the ambient temperatures to be expected during the holding time, if the foods were started at these temperatures rather than starting the 4 hour recommended hold time at 5°C (41°F).

Finally, the committee with the assistance of a scientific adviser looked at the pathogen modeling data to assess the growth potential at this ambient temperature within four hours. These growth data were also examined in light of other research findings related to the particular organism of concern. As with the FDA tomato study and recommendations, a one log

growth was considered the threshold of concern for the committee of the pathogen of most concern.

After examining all of the data gathered on the foods or food category, contributing operational experience with the retail level processes, a consensus position was determined on each item included in the charge. As a baseline for each food or food category, it was assumed that the original food or food category was in sound condition and the retail establishment was following all other Food Code requirements in regard to personnel, food, equipment and facilities. The detailed committee minutes and recording links provided through the Council III Chair and Co-Chair to the board highlight the examination of each food and food category before a consensus position was reached.

During the discussion of the assigned foods and food categories, it was determined that no other time was available for the committee to explore the part of the charge "charge shall include, but not be limited to." It was discussed by the committee that specific food and food category listing, as presented in the charge at the 2012 biennial meeting, was probably not the best way to amend Food Code's list of foods exempt from starting time control with temperature holding requirements. With more scientific research and study, by FDA or a scientific committee, this exemption could probably be made in a more systematic way over broader categories of foods.

b. **Consultations Outside the Committee:**

Rich Linton, PhD., North Carolina State University, College of Agriculture and Life Sciences, and CFP Time as a Public Health Control Committee Chair, 2002-2004

Kathy Glass, PhD., University of Wisconsin, Food Research Institute

Don Zink, PhD., Food and Drug Administration, Center for Food Safety and Applied Nutrition

c. Outcome / Disposition of Charge:

The committee used the recommended IFT and NACMF reports, pathogen modeling programs, outbreak investigation reports, CDC FOOD database, and other scientific references in their deliberations of the foods and food categories in the charge.

The committee recommends two issues be submitted to the 2014 biennial meeting as outlined in this report, in addition to the issue to acknowledge the final report.

2. Recommendations for Consideration by Council:

a. Committee Future:

Committee has completed the 2012 Conference charge and there is no need to continue it.

3. CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

The following issues will be submitted:

a. "Report – Time as a Public Health Control (TPHC) Committee" - requesting the Conference to acknowledge the 2012–2014 Time as a Public Health Control Committee final report.

b. "TPHC 2 – Foods Starting at Room Temperature and Held Using TPHC". Cut tomatoes, cut cantaloupe, chopped leafy greens, opened canned tuna, and opened canned product used as a sole item may be started at room temperature and held up to four hours using the establishment's Time Control Plan.

c. "TPHC 3 – Foods Needing More Research for Using TPHC". These include retail-prepared chopped garlic and oil mixtures, hummus made from non-commercially prepared ingredients, and opened canned products used as an ingredient in a formulation. These foods and food categories are referred to FDA for further evaluation and research to determine if the following products can be held without cooling to 5°C (41°F) prior to using time as a public health control.

4. **Issue Supporting References:**

(Note: *The following supporting attachments/references were reviewed by the committee members and may not represent the views of the Conference for Food Protection.*)

a. General:

i. IFT's Evaluation and Definition of Potentially Hazardous Foods (2001) [http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm094141.htm]

ii. NACMF Parameters for Inoculated Pack/Challenge Studies (2009) [http://www.fsis.usda.gov/wps/wcm/connect/3b52f9c0-0585-4c0a-abf2-b4fc89a9668c/NACMCF_Inoculated_Pack_2009F.pdf?MOD=AJPERES&CACHEID=58c8f975-2193-4f00-873e-8739fec1f1e1]

iii. USDA Pathogen Modeling Program version 7 (2003) [http://ars.usda.gov/services/docs.htm?docid=6786]

iv. ComBase - a Combined Database for Predictive Microbiology [http://www.combase.cc/index.php/en/]

v. CDC National Outbreak Reporting System (NORS) Foodborne Outbreak Online Database (FOOD) [http://wwwn.cdc.gov/foodborneoutbreaks]

b. Cut Tomatoes:

i. FDA Program Information Manual (PIM): Retail Food Protection Storage and Handling of Tomatoes. Page Last Updated: 09/04/2013. [http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm]

ii. Modeling the Growth of Salmonella in Cut Red Round Tomatoes as a Function of Temperature. Wenjing Pan and Donald W. Schaffner, Journal of Food Protection, Vol. 73, No. 8, 2010, Pages 1502–1505. [http://www.ingentaconnect.com/content/iafp/jfp/2010/00000073/00000008/art00013]

c. Cut Cantaloupe:

i. FDA Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons - Draft Guidance -July 2009 [http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm174171.htm]

ii. FDA-Retail Food Safety PIM - Safe Handling Practices for Melons – 2001

[http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm217290.htm]

iii. Growth kinetics of Listeria monocytogenes and spoilage microorganisms in fresh-cut cantaloupe. Fang T, Liu Y, Huang L. Food Microbiology, 2013 May;34(1):174-81.
[http://www.ncbi.nlm.nih.gov/pubmed/23498195]

iv. Development and validation of a mathematical model for growth of pathogens in cut melons. Li D, Friedrich LM, Danyluk MD, Harris LJ, Schaffner DW. Journal of Food Protection, 2013 Jun;76(6):953-8.
[http://www.ingentaconnect.com/content/iafp/jfp/2013/00000076/00000006/art00005]

d. Chopped Leafy Greens:

i. Quantitative Assessment of the Microbial Risk of Leafy Greens from Farm to Consumption: Preliminary Framework, Data, and Risk Estimates, Michelle D. Danyluk and Donald W. Schaffner, Journal of Food Protection, 2011; 74(5):700–708.
[http://www.ncbi.nlm.nih.gov/pubmed/21549039]

ii. FDA Program Information Manual Retail Food Protection: Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments - July 7, 2010
[http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm]

iii. Survey of temperature and consumption patterns of fresh-cut leafy green salads: risk factors for listeriosis. Carrasco E, Pérez-Rodríguez F, Valero A, García-Gimeno RM, Zurera G. Journal of Food Protection, 2007 Oct;70(10):2407-12.
[http://www.ncbi.nlm.nih.gov/pubmed/17969627]

e. Opened Canned Tuna:

i. Effect of Storage Conditions on Histamine Formation in Fresh and Canned Tuna. Maurice Kerr, Paul Lawicki, Sylvia Aquirre and Carl Rayner. State Chemistry Lab, Public Health Division, Victorian Government Department of Human Services, 2002.
[http://www.health.vic.gov.au/archive/archive2011/foodsafety/archive/downloads/histamines_fishstorage2002.pdf]

ii. Bacterial Growth and Histamine Production in Tuna Salad Preparations. Susan McCarthy, Kristin Butler, Ronald Benner, Jr. FDA Poster, International Association of Food Protection, 2012.
[https://iafp.confex.com/iafp/2012/webprogram/Paper1621.html]

f. Retail Prepared Chopped Garlic And Oil Mixtures:

i. FDA – Safe Practices for Food Processes, Chapter IV: Outbreaks Tables - [http://www.fda.gov/food/foodscienceresearch/safepracticesforfoodprocesses/ucm091270.htm]

ii. Garlic Safe Methods to Store, Preserve, and Enjoy, Linda J. Harris, University of California, Davis Publication 7231, November 1997. [http://anrcatalog.ucdavis.edu/pdf/7231.pdf]

iii. Toxin Production by Clostridium botulinum Type A Under Various Fermentation Conditions. Lynne S. Siegel, Joseph F. Metzger, Applied and Environmental Microbiology, Oct. 1979, p. 606-611. [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC243547/pdf/aem00203-0050.pdf]

iv. Conservative Prediction of Time to Clostridium botulinum Toxin Formation for Use with Time-Temperature Indicators to Ensure the Safety of Foods. Guy E. Skinner, John W. Larkin, Journal of Food Protection, Vol. 61, No.9, 1998, Pages 1154-1160. [http://www.ncbi.nlm.nih.gov/pubmed/9766067]

g. Hummus:

i. Viability of salmonella and Listeria monocytogenes in Delicatessen Salads and Hummus as Affected by Sodium content and Storage Temperature. Alali, Walid Q; Mann, David A; Beuchat, Larry R. Journal of Food Protection 75.6 (June 2012): 1043-56. [http://www.ncbi.nlm.nih.gov/pubmed/22691471]

ii. Growth and Survival of Listeriay monocytogenes in two Traditional Foods from the United Arab Emirates. V.S. Gohil; M.A., Ahmed; R. Davies; R.K. Robinson. Food Microbiology (1996, 13): 159-164. [http://www.ingentaconnect.com/content/ap/fd/1996/00000013/00000002/art00020]

iii. Hazard Analysis and Critical Control Point Generic Models for Some Traditional Foods, a Manual for the Eastern Mediterranean Region. World Health Organization. [http://applications.emro.who.int/dsaf/dsa1100.pdf]

iv. Multistate Outbreak of Salmonella Serotype Bovismorbificans infections Associated with Hummus and Tahini – United States, 2011. Morbidity and Mortality Weekly Report. Nov. 23, 2013, 944-947. [http://www.cdc.gov/mmwr/pdf/wk/mm6146.pdf]

v. Surveillance for Foodborne Disease Outbreaks – United States, 2007. Morbidity and Mortality Weekly Report. Aug. 13, 2010, 973-979.
[http://www.cdc.gov/mmwr/pdf/wk/mm5931.pdf]

5. COMMITTEE MEMBER ROSTER (attached)

2012-14 TPHC Committee Roster.xls