

**Conference for Food Protection
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Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Title:

Determining the Disposition of Refrigerated PHF (TCS food) above 5°C (41°F)

Issue you would like the Conference to consider:

Food establishments and regulators often have to make decisions about the safety of refrigerated PHF (TCS food) when product temperature has increased above 5°C (41°F). For example, during emergency power outages, refrigerated food may have a slight increase in temperature until actions can be taken to maintain the food at 5°C (41°F). During these times, it is equally important that food establishments be able to safely sell food to consumers, donate food to the community and prevent the needless destruction of safe food.

Food establishments and regulators need science-based procedures for determining when refrigerated PHF (TCS) food can be safely sold and when it should be destroyed or re-conditioned in the event there is an increase in the food temperature above 5°C (41°F). Such a provision in the FDA Food Code would be most useful in emergency situations such as during a power outage.

This provision would provide disposition recommendations such that refrigerated PHF (TCS) food that exceeds 5°C (41°F) for a specified time and temperature combination can be safely sold, and establish the limits of time and temperature when such food must be destroyed or reconditioned. Based on science, such provisions would offer a sound basis for making disposition decisions of refrigerated PHF (TCS) food, especially during emergency situations.

Food Code Part 3-7, *Contaminated Foods*, should be renamed *Disposition of Food*. This Part of the Food Code should also be revised to include science-based recommendations for the disposition options for refrigerated PHF (TCS) food that is above 5°C (41°F) but which can still be safely sold.

During times of emergencies and follow-up recovery, food establishments and regulators often consult the *CFP Emergency Action Plan for Retail Food Establishments*¹ (See Reference #1 on the list of Attachments) including the section titled *Interruption of Electrical Service, Part III, Recovery*, on page 10. This guide includes a table labeled "Cold Foods Internal Temperature Guidance" which offers guidance for handling refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F). The guidance provided is not based on science nor is it reflective of recommendations in the Food Code. The Food Code is of little use in such situations since it does not provide specific

recommendations on the disposition options for such food. Having consistent, science-based recommendations in both the Food Code and the *CFP Emergency Action Plan for Retail Food Establishments* for disposition of refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F) would benefit regulators and food establishments, while protecting and serving the public.

Public Health Significance:

The time and temperature parameters for this recommendation were based on the considerable body of science available regarding growth of pathogens at various time/temperature combinations and the current recommendations in the Food Code. It also includes a variety of conservative (fail-safe) assumptions.

The decision was made to review two different data sets regarding pathogen growth, and to use the more conservative numbers when developing disposition recommendations. The first body of science referenced was the 2004 CFP report from the "Time Only as a Public Health Control Committee - Council III"² (See reference #2 on the list of Attachments) which used the USDA-Pathogen Modeling Program (PMP) to predict the time for a 1-log increase in *Listeria monocytogenes* (*Lm*) concentration. The second set of scientific data includes model predictions from the ComBase predictor model, found at:

- The results from both the PMP and ComBase models are included in the *Predicted Time for the Increase in Growth of Listeria monocytogenes (Lm) at Various Temperatures* tables.³ (See reference #3 on the list of Attachments) The 2004 Committee Report using the USDA PMP shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 53.9 hours and 34.7 hours, respectively. (Table 4, located at Reference #3 on the list of Attachments) The results from the ComBase predictor model shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 30 hours and 18 hours, respectively. (Table 1, located at Reference #3 on the list of Attachments)

The predicted times using the ComBase model are less than those shown for the PMP, primarily due to the assumption that no lag time occurs. The ComBase predictor model also has the added benefit of being extensively validated with published data for actual pathogen growth in foods. For example, the ComBase database contains 20 growth rates for *Lm* growth in foods, between 8°C and 12°C, pH 6.5 to 7 and water activity between 0.99 and 1.00. In almost every case the ComBase growth rate prediction was equal to or faster than the actual measured growth rate in the food product. In a related analysis, *Lm* is known to be a risk in processed meats. The ComBase database contains 153 potential data sets on *Lm* in processed meats. From those 153 data sets (growth curves), 68 showed growth or were in the range encompassed by the model, further demonstrating good validation of the ComBase model.

Additionally, when making the calculations below, four safety factors were built in:

- The scenario assumes the food is held at 45°F or 50°F for the complete time. It does not take into account the time at which the food is less than 45°F or 50°F as it equilibrates with the ambient or surrounding temperature.
- The model assumes ideal growth conditions in the food.
- The model assumes no lag time, even though most scientific literature does show a lag time for *Lm* growth in foods.

- The model assumes all food, both raw and RTE, contain *Lm* at the onset even though RTE foods should not contain pathogens.

The FDA Position Paper in support of using time and temperature for public health control of PHF (TCS) food can be found in the Food Code *Annex 3 - Public Health Reasons/Administrative Guidelines, 3-501.19, Using Time as a Public Health Control (419-422)*. The same assumptions used to support *Time as a Public Health Control* in the current Food Code were considered in developing this proposal. Some relevant points from the position paper that provided assumptions for the proposal are cited below:

- Food held without temperature control equilibrates with the environment. Most models are based on the assumption that the food product spent all of the time at the highest temperature. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly. This assumption adds an extra margin of safety into the predictive models.
- When evaluating the safety of time and temperature control, parameters must be selected to create a conservative (fail-safe) scenario for the potential for pathogen growth.
- When evaluating pathogen growth in refrigerated PHF (TCS) food, it is recommended to use *Listeria monocytogenes (Lm)* is the primary organism of concern due to its psychotropic properties.
- A 1-log growth increase in *Lm* should be used as the critical limit.

To establish the most fail-safe approach to disposition, it was decided to use the data from the ComBase predictor (with no lag time) because it resulted in more conservative estimates and because the model is extensively validated. The conservative time/temperature parameters discussed above should provide a fail-safe system for determining the safe disposition of refrigerated PHF (TCS food) that exceeds 41°F. However, because this recommendation is intended to provide procedures whereby food can be restored to 41°F and safely sold, the authors opted to use an even more conservative margin of safety. Therefore, the decision was made to use the ComBase predictor for time/temperature combinations that would result in a 0.5-log increase in *Lm*. These results show the time needed for a 0.5-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 15 hours and 9 hours, respectively (Table 1, located at Reference #3 on the list of Attachments).

A half-log is generally accepted as the resolution limit of microbial testing, resolution being the capability of making distinguishable two sets of results. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2010, JFP 73:140-202) has, in general, used <1 log as the criteria for determining the absence of measurable growth of pathogens of concern⁴ (See Reference #4 on the list of Attachments) Furthermore, in the same publication, NACMCF has stated that the growth of pathogens at less than a 1-log increase "reflects the inherent variation that exists with enumeration of microorganisms." ⁴ (See Reference #4 on the list of Attachments)

Using a half-log increase as the critical limit means that the disposition criteria are based on the assumption that food which is allowed to exceed 41°F for a specified time and returned back to 41°F within a specified time will have the same microbiological profile as that which was maintained at 41°F for the same period of time. In other words, there is essentially no microbiological difference, and no increased risk, in the food continually held at 41°F and that which is handled according to the recommended disposition criteria. The ComBase predictor model was again used to verify these time/temperature combinations,

only using a 0.5-log *Lm* growth increase (Table 1, located at Reference #3 on the list of Attachments.) All other assumptions remained the same.

The new provision would allow refrigerated PHF (TCS food) that has been held up to 45°F and brought back to 41°F in a total of 15 hours or, held up to 50°F and brought back to 41°F in a total of 9 hours, to be sold. At these times and temperatures, there is a significant safety margin, especially when using a half-log *Lm* increase as the critical limit.

Recommended Solution: The Conference recommends...:

1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended using strike through to remove language and underline for new language as follows:

Food Code Part 3-7 *Contaminated Food* be renamed *Disposition of Food* as follows:

~~3-7 Contaminated Food~~ Disposition of Food

AND:

Subpart 3-701 be renamed *Disposition of contaminated food*; the Sections and Paragraphs A-D under 3-701 remain the same; and a new Subpart 3-702 be added named *Disposition of Refrigerated PHF (TCS food)* as follows:

Subparts

- 3-701 Disposition of Contaminated Food
- 3-702 Disposition of Refrigerated PHF (TCS food)

AND:

The new Subpart 3-702 will include a Section and Paragraphs explaining the time/temperature parameters that can be used when determining the disposition of refrigerated PHF (TCS food) held at temperatures above 41°F but still eligible for sale as indicated below:

3-702 Disposition of Refrigerated PHF (TCS food)

3-702.11 Determining when Refrigerated PHF (TCS food) can be Safely Sold Following an Increase in Cold Holding Temperature

(A) Refrigerated PHF (TCS Food) can be safely held and sold at temperatures above 5°C (41°F) provided:

(1) Written procedures are in place to specify the methods used to demonstrate compliance with Subparagraphs B and C of this section

(B) Refrigerated PHF (TCS food) can be held and sold at a temperature up to 7.2°C (45°F) provided:

(1) The total time during which the food is above 5°C (41°F) but not over 7.2°C (45°F) is 15 hours or less

(2) By the end of 15 hours the food has returned to 5°C (41°F) or lower

(3) The food shall be monitored to ensure the warmest portion of the food does not exceed 7.2°C (45°F) during the 15-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 7.2°C (45°F) during the 15-hour period:

(4) The food shall be destroyed if at the end of 15 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.

(C) Refrigerated PHF (TCS food) may be held and sold at a temperature up to 10°C (50°F) provided:

- (1) The total time during which the food is above 5°C (41°F) but not over 10.0°C (50°F) is 9 hours or less
- (2) By the end of 9 hours the food has returned to 5°C (41°F) or lower
- (3) The food shall be monitored to ensure the warmest portion of the food does not exceed 10.0°C (50°F) during the 9-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 10.0°C (50°F) during the 9-hour period;
- (4) The food shall be destroyed if at the end of 9 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.

AND:

2. The Conference further recommends revising the *CFP Emergency Action Plan for Retail Food Establishments, Interruption of Electrical Service, Part III. Recovery*, on page 10, by removing the table labeled "Cold Foods Internal Temperature Guidance" and replacing it with the same language as above in the new Food Code Subpart 3-702 *Disposition of Refrigerated PHF (TCS food)*.

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Attachments:

- "References cited in Attachment: "Disposition of Refrigerated TCS Food""

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.