

From: Barbara M. Gerzonich [mailto:bmg02@health.state.ny.us]

Sent: Monday, May 17, 2010 4:40 PM

To: Michelle Robinson

Cc: Christine A. Westerman; Brian D. Devine; Michael J. Cambridge; mary.leong@fda.hhs.gov; Edmund R. Carloni; Darby J. Greco; Beth Torin

Subject: Fw: TPHC Rules - Article 81 proposed amendments

Michelle,

Here are the more detailed comments which you recently requested:

- 1) 81.03 Definitions - Section y: add the word "cut" to the phrase leafy greens; Add "cut melon" to the definition; Add a definition for "cut leafy green" in the definitions section which is consistent with the FDA definition
- 2) 81.10 Time as a Public Health Control - (a) If the intent is to substitute TCS for potentially hazardous foods, I recommend adding the 2 terms side by side during the transition period in this section.
- 3) 81.10, 4(a) - for the 4(A) 4 hour holding, I recommend eliminating the need for writing the time the food is removed from temp. control & the discard time. stay consistent with the FDA Model Food Code with just the discard time.
- 4) Add a section on 81.10 which describes what will happen to food in unmarked containers, consistent the FDA Model Food Code, Section 3-501.19(B) (4)
- 5) There's no scientific reasoning for prohibiting time as a public health control in temporary, mobile or buffets so recommend removing the prohibition.
- 6) The FDA Model Food Code does not prohibit TPHC for TCS foods of aquatic animals, shellfish & packaged, smoked fish. I suggest adopting language which is consistent with the FDA Model Food Code. If you want to discuss, please let me know.

Barb

----- Forwarded by Barbara M. Gerzonich/BCSFP/DEP/CEH/OPH/DOH on 05/17/2010 04:24 PM -----

Michelle -

conceptually, a great move forward!

1) does the operator really need to label both the start time & the end time ? what about unlabeled foods? what's the science/reasoning behind 81.10 (b) 2 & 3 stating no TPHC at mobiles or excluding vacuum packaged foods. There doesn't seem to be a parallel in the FDA Model Food Code for these additional elements.

2) do you have a definition for "leafy greens" as a TCS food. It's my impression that FDA means "cut leafy greens" & the cut is more than the cut which separates the leaf from the root. also herbs such as basil & cilantro are NOT included. so I suggest some kind of definition for leafy green consistent with FDA. It's my understanding that they have some leafy green guidance (consistent with the sliced tomato guidance issued 2 years ago) going through the review process. we decided not to go forward with the leafy green implementation until their guidance was issued so we'd have a clearer picture of what they intend.

will probably have staff review again in case I've missed something but here's my immediate comments. way to go!

Barb

From: Leong, Mary H [mailto:Mary.Leong@fda.hhs.gov]
Sent: Tuesday, April 27, 2010 6:06 PM
To: Michelle Robinson
Cc: O'Malley, Elizabeth; Duffill, Raymond A
Subject: RE: TPHC

Hi Michelle,

I think it is a great move in the right direction. Food Code Section 3-501.19 allows the use of time as a public health control for a working supply of PHF/TCS food before cooking and RTE PHF/TCS food. It requires a written procedure to be maintained in the FSE and available to regulatory authority upon request. The written procedures should specify methods of compliance with requirements specified in 3-501.19(B) time up to 4 hours and (C) time up to 6 hours AND 3-501.14 for food that is prepared, cooked, and refrigerated before TPHC is used. It also prohibit the use of TPHC for raw eggs in an establishment that serves highly susceptible population.

PHF/TCS Food is defined in the Code as (1) food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation and (2) includes:(a) An animal food that is raw or heat-treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and (b) food designated as Product Assessment Required (PA) in the pH and Aw interaction tables. It exclude, (a) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae; (b) 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; (c) A food designated as non-PHF/non-TCS food in the pH and Aw interaction tables; (d) A food with lab results that shows that is non-PHF/non-TCS food; (e) A food that does not support the growth or toxin formation of pathogenic microorganisms even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

In the notice of public hearing, the definition of PHF/TCS food and other places referencing that definition omits "cut melons", "cut" leafy greens, and more importantly the pH and Aw interaction tables. For TPHC, the requirement for a written procedures is missing. Also, it only mentioned the use of TPHC for RTE foods and does not allow for a working supply of PHF/TCS food. There were prohibitions of the use of TPHC beside raw eggs for establishment serving HSP. This is fine but it may be useful to include the rationale for the prohibition. I also find the part where it requires the food to be consumed and discarded within the 4 hours and 6 hours time to be confusing.

Please see specific comments in the attachment. If you have any questions, please let me know. I will be out of the office tomorrow and Thursday but will be checking emails. I will be back Friday if you want to discuss any issues.

Thanks for the opportunity to comment.

Mary