

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 044
Issue: 2010 I-017**

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

All information above the line is for conference use only.

Title:

Criticality Implementation&Education Comm. -Timely Correction of Violations

Issue you would like the Conference to consider:

The FDA Criticality Work Group re-designated each Food Code provision into one of three terms. The three terms were used to rank the provisions in the Food Code according to how direct their relationship was to preventing, eliminating or reducing to an acceptable level, hazards that cause foodborne illness or injury. Out of compliance risk factors and Food Code interventions have a direct relationship and good retail practices have an indirect relationship. The timely correction sections in Chapter 8 that specify how long an operator has to correct a violation still has only two categories and does not adequately reflect the three separate terms now being used.

Sequentially, a need exists to combine existing Code sections 8-405.11 (Timely Corrections of Priority or Priority Foundation items) with 8-406.11 (Time Frame for Correction for Core Item violation), and add a third section to correspond with the new three tier structure in the Food Code. The new sections will be numbered 8-405.11, 8-405.12, and 8-405.13.

Public Health Significance:

The three terms defining criticality will enable both regulators and industry to prioritize their time and efforts. These three terms are distinct with Priority Items directly controlling hazards associated with food borne illness or injury. Priority Foundation Items support, facilitate or enable other Priority Items; and Core Items are general sanitation, maintenance, operations control, and facility and equipment design.

These three categories are based on risk ranking, with Priority violations being the highest risk and Core the lowest risk. There are currently only two categories defining the timely corrections of these violations, based on the previous critical and non-critical terms. Priority and Priority Foundation are currently lumped together even though the risk ranking for the two is not the same. For the purpose of training and compliance, the time for correction should also be a new three- tier system to be consistent with the level of risk clearly identified.

There can be punitive penalties associated with the highest risk category. These penalties can include fines, re-inspections, and suspended or revoked license with what used to be critical violations. Placing all Priority and Priority Foundation violations together in Chapter

8 will result in confusion with both regulatory and industry thinking all of the violations carry the same risk and legal weight.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting revision and/or addition to the following three sections in Chapter 8, Compliance and Enforcement in the FDA Food Code: 8-405.11, 8-405.12 and 8-405.13 (new language is in underline format; deleted language in strike through).

Violation of Priority Item ~~or Priority Foundation Item~~ 8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct a violation of a priority item ~~violations or priority foundation item~~ of this Code and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit. ^{Pf}

(B) *Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame for corrective actions that have been initiated but not yet completed, not to exceed 72 hours ~~10 calendar days~~ after the inspection, for the permit holder to correct violations of a priority item ~~or priority foundation item or HACCP plan deviations~~ violations.*

Violation of Priority Foundation Item 8-405.12 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a permit holder shall at the time of inspection immediately initiate and correct priority item violations of this Code.

(B) *Considering the nature of the violation involved or the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct violations of a priority item violations.*

Core Item Violation ~~8-406.11~~ 8.405.13 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the permit holder shall correct core items violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

Submitter Information:

Name: Rick Barney, Co-Chair
Organization: Criticality Implementation and Education Committee
Address: Sweetbay Supermarket 3801 Sugar Palm Dr.
City/State/Zip: Tampa, FL 33618
Telephone: 813-620-1139 x332 Fax: 813-627-9765
E-mail: rbarney@sweetbaysupermarket.com

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