

**Conference for Food Protection
2018 Issue Form**

Issue: 2018 I-020

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Variance Procedure Requirements

Issue you would like the Conference to consider:

A recommendation is being made to clarify the requirements of variance procedures that are granted, as stated in Section 8-103.12 of the FDA Food Code.

The FDA Food Code Section 8-103.12 discusses what is required of the permit holder once a variance or HACCP Plan has been submitted. Clarification needs to be made that variance procedures that are submitted must be followed, just as HACCP Plan documents and procedures must be followed.

Public Health Significance:

The FDA Food Code explains compliance and enforcement requirements in Chapter 8. Specifically, in Section 8-103.12, the Food Code says "If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver^P..."

This section makes it clear that when a HACCP Plan has been submitted and approved, the facility must comply with the HACCP Plan and procedures. However, the same requirement is not clear when a variance is obtained without a HACCP Plan.

There are many examples of variances that can be submitted and obtained without a HACCP Plan, where it is still vital to follow the submitted procedures. If a challenge study has been submitted using the Guidance for Inoculated Pack/Challenge Study Protocols as determined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), there are time and temperature parameters set for those studies. If an establishment does not comply with the time and/or temperature parameters that are used in a challenge study, the safety of the food could be compromised. In these situations,

there needs to be clear expectations that enforcement action could be taken if the time or temperatures fall outside approved parameters.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Section 8-103.12 of the most current edition of the Food Code be amended to include clarifying language for variance procedures that do not require a HACCP Plan as follows (new language is underlined):

"If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures, or other variance procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver^P..."

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