**Conference for Food Protection**

**2020 Issue Form**

**Issue: 2020 III-014**

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| **Council Recommendation:** | Accepted asSubmitted |  | 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:**

PAC 5–Amend Food Code Reference Approved Documents in FDA Food Code Annex 3

**Issue you would like the Conference to consider:**

Inclusion of the committee generated guidance document entitled, "Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators", the "Checklist for Retail Establishment Challenge Study", and the "Challenge Testing Worksheet to Determine Microbiological Stability of Formulation" in the FDA Model Food Code Annex 3.

**Public Health Significance:**

Using the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) protocol can be difficult for both operators and regulators to understand. This leads to challenges for regulatory authorities, to provide approval for challenge studies, and retail food establishments, to know how to move forward with completing a challenge study. Providing tools for retail food establishment challenge studies will increase compliance with FDA Food Code and help to ease the burden for operators and regulators. Three documents were created by the Product Assessment Committee. Inclusion these documents in Annex 3 of the FDA Food Code will assist retail food establishment operators and regulators in accessing this information.

**Recommended Solution: The Conference recommends...:**

The Conference recommends....

A letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to all of the approved documents/tools from the Product Assessment Committee at the end of the section as follows:

**1-201.10 Statement of Application and Listing of Terms.**

**(B) Terms Defined**

**Time/Temperature Control for Safety Food**

When a "Product Assessment" is indicated in the chart, a challenge study may be done to determine the shelf life of the product, or the time a product can be maintained at room temperature. Documents have been developed through the Conference for Food Protection (CFP) Product Assessment Committee to assist operators and regulators with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Parameters for Determining Inoculated Pack/Challenge Study Protocols. These documents include Guidance Document on Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators, Checklist for Retail Establishment Challenge Study, and Challenge Testing Worksheet to Determine Microbiological Stability of Formulation. These documents can be found on the CFP website.

Note: All documents are attached to "Report - Product Assessment Committee (PAC)" and submitted for CFP approval and posting in Issues "PAC 2-4".

**Submitter Information 1:**

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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.