Proposal Subject: Laboratory Methods

Specific NSSP Guide Reference: NSSP Guide Model Ordinance Chapter XVI. Post-Harvest Processing A. (1) (a)

Text of Proposal/ Requested Action

2003 NSSP Model Ordinance Chapter XVI Post Harvest Processing A (1) (a)

For processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in the product that has been subjected to the process shall be non-detectable (<30 MPN/gram), to be determined by the use of ~~the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al., as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or other~~ method**s** approved **by the Laboratory Methods Review Committee** for NSSP use.

It has been reported by laboratories that the reagents for the Tamplin EIA test are not readily available. Other testing procedures are needed to do perform the analysis of *Vibrio vulnificus*. However, since not all methods listed in the *Bacteriological Analytical Manual* (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program.

Public Health Significance: Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and in participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.

Cost Information (if available): None

Action by 2005 Task Force III Recommended referral of Proposal 05-305 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force III.

Action by ISSC Executive Board August 19, 2005 Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.

Action by USFDA Concurred with Conference action.

Action by 2007 Laboratory Methods Review Committee Recommended referral of Proposal 05-305 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 Task Force III Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-305.

Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 Laboratory Methods Review Committee	Recommended no action on Proposal 05-305. Rationale: The proposed new language is inconsistent with the ISSC Constitution, Bylaws and Procedures and the remainder of the proposal is more appropriately addressed in Proposals 07-103 and 09-229.
Action by 2009 Task Force III	NOTE: The action taken by Task Force III was to only address the proposed new language in Proposal 05-305. Recommended adoption of the Laboratory Methods Review Committee recommendation regarding proposed new language in Proposal 05-305. Task Force III did not take action on the remainder of Proposal 05-305. The remainder of Proposal 05-305 was addressed by Task Force I.
Action by 2009 Task Force I	Recommended no action on the remainder of Proposal 05-305. Rationale: The remainder of Proposal 05-305 is more appropriately addressed by Task Force I and II action on Proposals 07-103 and 09-229.
Action by 2009 General Assembly	Adopted recommendations of Task Force III and Task Force I on Proposal 05-305.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 05-305.