

Proposal Subject:	Laboratory Methods (<i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i>)
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter XVI. Post Harvest Processing
Text of Proposal/ Requested Action	<p>A. If a dealer elects...</p> <p>(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.</p> <p>(a) The dealer must demonstrate that the process reduces the level of <i>Vibrio vulnificus</i> in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction, to be determined by use of the <i>Vibrio vulnificus</i> FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA <i>Bacteriological Analytical Manual</i>, 7th Edition, 1992, or <u>other method approved for NSSP use the MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA alkaline phosphatase labeled gene probe (vvhA).</u></p> <p>(b) The dealer must demonstrate that the process reduces the level of <i>Vibrio parahaemolyticus</i> in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction <u>Vibrio parahaemolyticus levels are to be determined using the MPN format with confirmation by biochemical analysis, gene probe methodology, or PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.</u></p>

Public Health Significance:

Cost Information (if available):

Action by 2007 Task Force I	Recommended referral of Proposal 07-103 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 Laboratory Methods Review Committee	Recommended no action on Proposal 07-103. Rationale: Adequately addressed by Proposal 09-229.
Action by 2009 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 07-103.

**Action by 2009
General Assembly** Adopted recommendation of 2009 Task Force I on Proposal 07-103.

**Action by USFDA
02/16/2010** Concurred with Conference action on Proposal 07-103.