

Proposal Subject	Validation/Verification of PHP
Specific NSSP Guide Reference	Guidance Documents, Chapter IV.04 Validation/Verification Interim Guidance
Text of Proposal/ Requested Action	The validation/verification workgroup has identified a need for guidance in the evaluation of PHPs that are validated using initial loads other than the currently recommended 100,000/gram adjusted geometric mean. Alternative approaches to the validation/verification protocol for PHP should be considered. One possible approach is the use of a log reduction criteria rather than a specific initial level and end point criteria. If this is determined to be a feasible approach, the workgroup will present a specific alternative protocol for validation and verification of PHPs to the Conference. The protocol will include guidance to be used by FDA and State Regulators in evaluating PHP validations.
Public Health Significance	Many food commodities are regulated based upon a specified log reduction of a particular pathogen. This log reduction approach could be applied to <i>V. vulnificus</i> and <i>V. parahaemolyticus</i> levels to achieve an appropriate level of public health protection in PHP shellfish.
Cost Information (if available)	None
Action by 2005 Task Force II	Recommended referral of Proposal 05-204 to the Validation/Verification Workgroup with instructions to continue reviewing alternative validation approaches using initial loads other than 100,000 per gram. Appropriate approaches should be reported to the Executive Board for interim approval.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by Executive Board	The ISSC Executive Board adopted a revised approach with interim approval. The revised approach was submitted for consideration as Proposal 07-208.
Action by 2007 Validation/ Verification Workgroup	Recommended to Task Force II no action if Proposal 07-209 is adopted.
Action by 2007 Task Force II	Recommended no action on Proposal 05-204. Rationale – addressed in Proposal 07-209.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.