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| Proposal Subject | Validation/Verification of PHP |
| Specific NSSP Guide Reference | Guidance Documents, Chapter IV.04 Validation/Verification Interim Guidance |
| Text of Proposal/ Requested Action | <p>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.</p> |
| Public Health Significance | <p>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.</p> |
| Cost Information (if available) | None |
| Action by 2005 Task Force II | <p>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.</p> |
| Action by 2005 General Assembly | Adopted recommendation of 2005 Task Force II. |
| Action by USFDA | Concurred with Conference action. |