Proposal Subject Laboratory Methods

Specific NSSP Guide Reference Public Health Reasons and Explanation, Chapter III Laboratory @ .02 Methods

Text of Proposal/ Requested Action American Public Health Association (APHA) Recommended Procedures for the Examination of Seawater and Shellfish shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official references of the NSSP for the examination of shellfish for Vibrio cholerae, V. vulnificus, and V. parahaemolyticus is the FDA Bacteriological Analytical Manual (BAM) are the methods approved by the Laboratory Methods Review Committee and listed in Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory tests: Microbiological and Biotoxin Analytical Methods.

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 05-306 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.