Vibrio vulnificus PHT Validation/Verification Work Group Meeting Report (With VMC modifications)

The Work Group met on August 3, 2003. The Work Group's discussions on Proposal 03-212 centered on (1) clarification of several factors relating to the purpose and application of the proposed Validation Level 1 and 2, (2) the need to provide for verification procedures premised upon other methods (e.g. HACCP documented performance compliance with equipment design specifications relative to a predetermined scheduled process), and (3) the need to develop a microbiological sampling and analysis verification procedure to verify that a previously validated process is working properly, including the necessary number of samples and sub-samples and the associated pass/fail decision criteria and performance characteristics.

LEVEL 1 AND 2 VALIDATION DISCUSSIONS

It was resolved that Level 1 should be retitled "Process Validation" and is to be used for those PHT processes which have never been validated **or when there is a change to a previously validated process.** Level 2 validation has been retitled as "Revalidation" and is to be employed ~~when there has been a change in the process or~~ when a verification has failed in accordance with the verification decision tree. Further, a new validation category was added for equipment validation which allows for the provision of not requiring microbiological testing, provided that it can be reliably demonstrated that the equipment or process can meet predetermined process parameters.

VIBRIO PARAHAEMOLYTICUS CONSIDERATIONS

The fifth bulleted item under Validation dealing with Vp should be removed form the proposal. Nevertheless, a recommendation is to have the PHT Validation/ Verification Work Group next address Vp and other pathogens of concern.

VERIFICATION PROCESSES OTHER THAN MICROBIOLOGICAL ANALYSIS

The current verification sampling protocol decision tree attached to Proposal 03-212 needs to be either augmented to incorporate the concept of verification, when effective corrective actions are taken when HACCP records indicate a trend toward nonconformance to specific critical limits or critical limits are violated and/or when nonconformance is indicated specific processing protocols or failure of equipment to meet specific design criteria; or a new decision tree should be constructed for this purpose. There needs to be a consideration that expensive end-product sampling and microbiological analyses should not be the only verification approach, when effective corrective actions can be taken incorporating physical parameter changes (e.g., temperature, time, reprocessing, etc.) under a facility's operational HACCP plan.

DEVELOPMENT OF MICROBIOLOGICAL VERIFICATION PROTOCOLS

A verification approach protocol modeled after that used for the Validation protocol should be developed in terms of the number of samples to be drawn and analyzed, pass/fail decision criteria indicated and associated performance characteristics stated for the indicated protocol.