Verification Sampling Protocol Decision Tree

Monthly Sampling

- Pass
  - No Action
- Fail
  - Corrective Action Taken on the Product

Problems ID

- Fix
  - Problem
  - Process Adjustment
- No Problem ID
  - Validate
    - (No Labeling Claims in the Interim)

Re-Verify

- Pass
  - No Action
- Fail
  - 1. Corrective Action on Product
    2. Adjust Process / Investigate
  - Validate
    - (No Labeling Claims in the Interim)
Note: When a monthly verification fails, the verification must be reported within one week of failure

References for Vibrio parahaemolyticus Methods


References

Section IV Guidance Documents - Chapter IV Naturally Occurring Pathogens
02 Post-harvest Processing (PHP) Validation/Verification Guidance for V.v. and V.p.
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Description: Flow chart showing the post harvest processing verification sampling protocol and decision making process.

Collect monthly shellfish meat samples for process verification.

If the monthly samples pass, no action is required.

If the monthly samples fail, take the following measures; (1) Identify the problem, (2) Fix the problem, (3) re-verify the process by sampling. If the re-verification samples fail, no further action is required. If the re-verification samples fail, then; (1) Corrective action must be taken on the product, (2) The process must be investigated, (3) Any problems identified must be adjusted, and (4) The process shall be revalidated. No labeling claims can be made during the interim revalidation process.

If the monthly samples fail and no problem can be identified then; (1) Adjustments shall be made to the process, and (2) The process shall be revalidated. No labeling claims can be made during the interim revalidation process.