Use Validated Microbial Reduction Techniques

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Topics to be addressed

- What is Validation ?
- Why should we validate ?
- Options for Treatment
  - Elements to consider
- Benefits
- Summary

What is Validation ?

Definition

The documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results.

FDA

- **Validation:** confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled.

- **Process validation:** establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Why should we validate ?

Why should we validate ?

Should we test ?

Or

Should we treat ?

Testing

- Assume a defect rate <2%
- 15 x 25 g = 375g
- What is the risk of accepting a positive lot ?

77%

- McClure & Lee, AOAC 2011

Testing

- Assume a defect rate <2%
- 30 x 25 g = 750g
- What is the risk of accepting a positive lot ?

60%

- McClure & Lee, AOAC 2011

Treat without Validation

- If reduce the occurrence by ½
- Probability of finding Salmonella
  - 30 x 25 g = 750g was 77%
  - To achieve the same level (60%) as before
  - Require 60 sub-samples or 1500g

Treatment

- NACMCF recommends applying any process, treatment, or combination thereof, to reduce the most resistant *Salmonella* serotype “to a level that is not likely to present a public health risk under normal conditions of distribution and storage”

Options for Treatment ?

Options

- Ethylene Oxide
- Propylene Oxide
- Irradiation
- Steam
- Other effective heat treatments

Considerations

- The spice and final use
  - Application
  - Country
  - Customer
- The packaging
  - Effect on packaging
  - Packaging effect on treatment

Focus

- The Critical Control Point(s) lethality step to deliver the microbial reduction
  - Determine the critical limits
  - Confirm the consistency
  - Monitor and document action steps
- Selection of proper representative products

ASTA Validation Protocols

- ASTA/FDA Project to develop general protocols for use in validations
  - Assure Uniformity in approach
  - Shorten time for release of reconditioned products

Protocol Contents

- Scope
- General Provisions
  - Personnel
  - Equipment - General
  - Information on Monitoring Records
  - Process Validation
  - Reconditioning Documentation and Submission Requirements
- Resubmission Requirements
- References

Benefits

ASTA Protocols

- Industry - 2001
  - Reduced Testing
  - Shipments Expedited
    - Estimate a savings of $600/lot
    - Over $400,000 in 3 years
- FDA
  - Better Resource Allocation

FDA

- Compliance with FDA Guidance
- Recommend that firms

Validate any treatment or process used to adequately reduce Salmonella in a food

Industry

To provide clean, safe spices to their industrial, food service and consumer customers.

Summary

ASTA Recommends

The use of validated microbial reduction techniques

Elements

- Treatment Options, dependent on spice and final use
  - ETO or PPO
  - Irradiation
  - Steam
- Compliance with appropriate EPA tolerances
- Techniques should be used in accordance with EPA and label directions

Elements

- Validation should focus on the critical control point used to deliver a significant reduction (e.g., the lethality step)
  - Determine the critical limits (e.g., thermal and time parameters) required to achieve the target log reduction
  - Confirm the process equipment consistently delivers the critical limit parameters and/or target log reduction
  - Monitor the control points and have documented action steps should the parameters not be met
- Each process should be validated using representative products to which it will be applied

Questions