

A decorative graphic consisting of a thin yellow circle on the left side. A thick black left square bracket is positioned to the left of the circle, and a thick yellow right square bracket is positioned to the right of the circle. A horizontal bar with a light green-to-white gradient is placed across the middle of the circle, containing the main title text.

Use Validated Microbial Reduction Techniques

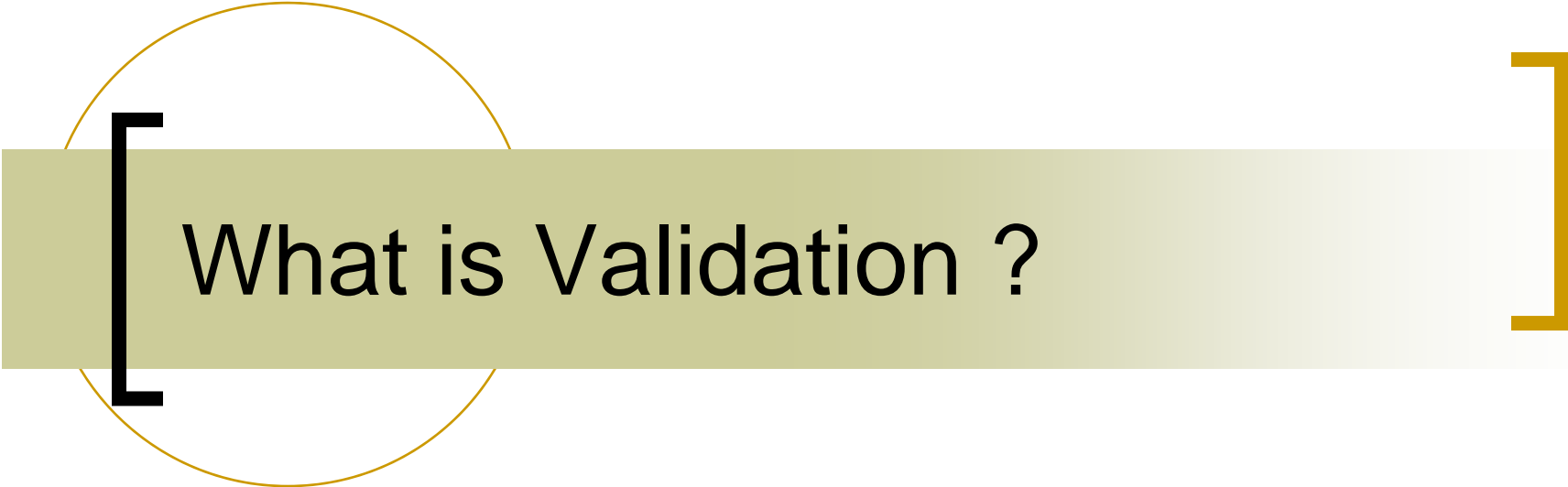
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ASTA Pre-Conference Workshop

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[Topics to be addressed]

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



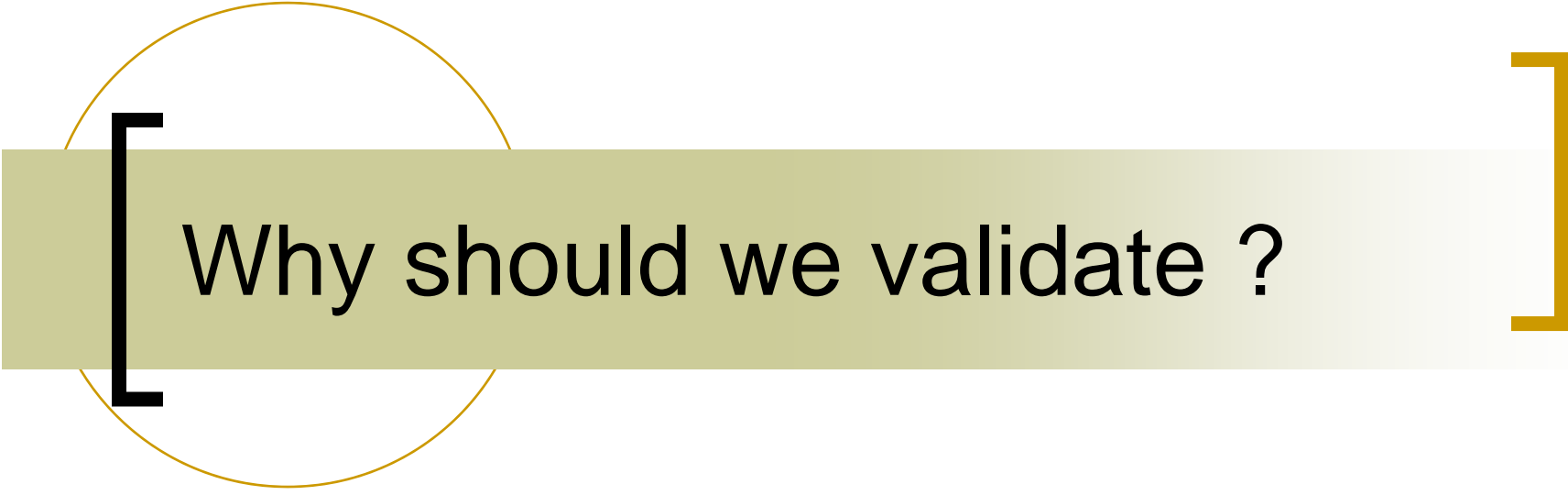
What is Validation ?

[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 $<2\%$
- $15 \times 25 \text{ g} = 375\text{g}$
- What is the risk of accepting a positive lot ?

77%

- McClure & Lee, AOAC 2011

[Testing]

- Assume a defect rate $< 2\%$
- $30 \times 25 \text{ g} = 750\text{g}$
- What is the risk of accepting a positive lot ?

60%

- McClure & Lee, AOAC 2011

[Treat without Validation]

- If reduce the occurrence by $\frac{1}{2}$
- 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