ASTA 2009
Annual Meeting and Trade Show
April 26-29, 2009
Loews Ventana Canyon Resort
Tucson, Arizona

Process Validations

Microbial Safety in Spices

2009 ASTA Annual Meeting

Validation Project

- Background
- Project
- Documents
- Benefits
- Recognition

1999 Observations

- Import
  - Heightened Focus on Pathogens
    - Food Safety
  - Port to Port Variation
  - Greater Emphasis on Process
    - HACCP
    - Personnel Changes

Impact

- Reconditioning application delays
  - Delays of 5-7 months
  - Disruption of trade
- Involved multiple importers
  - Confusing requests for information
  - Greater detail on applications
  - Proof of process

Actions

- Maryland Port Authority Meeting - 1999
- Meeting with FDA in early 2000
  - Identified need for uniformity
  - Need for validated processes
  - Background on the treatment options
- FDA Letter of February 10
  - Arrange site Tours, Meetings
  - Background presentations on Gas (ETO & PPO), Steam and Irradiation

Teams

- Overall – ASTA, FDA, Maryland Port Authority, Senator Mikulski's Office

- Process Teams
  - Gas, Steam and Irradiation
  - FDA & ASTA representatives as well as a volunteer industry site

By 2001

- Process Teams
  - Developed Protocols for the validation of Reconditioning Processes
    - Gas, Steam and Irradiation
  - Completed the Pilot Studies
  - Pilot Sites submitted Validations
- FDA
  - Developed internal training
  - Pilot done in Baltimore April 19th
  - Developed FDA Inspection Guide

General Protocol for the Validation of Microbiocidal Processes on Pathogen Contaminated Spices and Culinary Herbs

STEAM TREATMENT

CHAMBER TREATMENT
E.g. Ethylene Oxide and Propylene Oxide

GAMMA IRRADIATION

Protocol Contents

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

Introduction - Gas

This document is intended to be an informative reference for the practitioner of gaseous microbiocidal processes on spices and culinary herbs; and to simultaneously delineate guidelines for processing spices suspected or known to be contaminated with pathogenic microorganisms.

Scope - Gamma

- This document applies specifically to the reconditioning of **spices and culinary herbs**, which are either known or suspected to be contaminated with pathogenic microorganisms.
- The American Spice Trade Association publishes the list of Spices and Culinary Herbs covered by this document. A current copy of the list is available as Appendix I.
- Infective vegetative **pathogens** are referred to as pathogens and/or pathogenic microorganisms throughout this document.
- **Gamma** processing treatment is the microbiocidal process for which this document is intended.
- This document **does not address** occupational safety issues in the design or operation of the process equipment
- The **terminology and definitions** provided in Appendix IV are not intended for use outside of this Scope.

General Provisions

- Personnel
- Equipment & Facility
- Conditioning requirements - Gamma
- Monitoring records
- General Procedures – Gamma
- Process Validation

Resubmission Requirements

- Changes to product, process, packaging and equipment
- Processing equipment, product, or the processing conditions/parameters are changed in a manner that may impact the safety and treatment effectiveness
- If changes do not impact product safety, resubmission is not required. Support for the lack of impact must be on file at the site.

Appendices

I. ASTA Approved Spice List
II. Validation Submission Form
III. Reconditioning Submission Form
IV. Terminology Document
V. US FDA Form 766
VI. Lethality Calculations (Steam)

Forms

- Validation
  - Background & Scope
  - Justification for the worst case
  - Monitoring parameters
  - Definition of key parameters
- Routine Submission
  - Lot identification
  - Key parameters

“Scope”

II. Identification

a. Validation Date:	Previous Validation Date:
b. Is this the initial submission for the process? (circle one) YES or NO If NO, provide previous date and ID below.	
c. Validation ID:	Previous Validation ID:
d. List the facilities covered by this validation:	
e. Specifically identify the treatment chambers covered by this validation study:	
f. List products covered by this validation:	
g. Describe packaging covered by this validation:	

“Parameters”

a. Pressure

Description	Manufacturer	Model	Range	Accuracy
Please circle one:	Routine	Validation	Both	

b. Chamber temperature

Description	Manufacturer	Model	Range	Accuracy
Quantity and location(s).				
Please circle one:	Routine	Validation	Both	

c. Product temperature

Description	Manufacturer	Model	Range	Accuracy
Quantity and location(s). Attach placement diagrams.				
Please circle one:	Routine	Validation	Both	

“Worst Case”

VI. Bioburden of pathogenic microorganism

a. Results of bioburden testing (or literature reference search). Describe product bioburden level. Provide published references if applicable.
b. Describe any pretreatments used to reduce bioburden.

VII. Establishing worst-case processing conditions

a. Describe method used to determine worst-case treatment conditions. Sources for this information may include published reference data.
b. Describe the packaging types including material description (e.g., polywoven) to be covered by this process.
c. If more than one spice is covered by this validation, provide rationale used to determine worst case spice(s) to be studied, e.g., moisture content, antimicrobial properties, bioburden, penetration (heat or gaseous), previous treatment (gas, irradiation, heat).
d. If the validation study encompasses more than one packaging type describe the rationale for choosing the worst-case packaging. Consider penetration and permeability of primary packaging as well as the effect of packaging layers such as wrap and cardboard sheets.

“Routine Submission”

Sterilizer		
Parameter	**Observed**	**Validated Tolerance**
Sterilant gas concentration		
Sterilant gas weight		
Sterilant dwell temperature		
Sterilant dwell time		
Product temperature		
Relative humidity (if used)		

Terminology

Aerate/Aeration. Part of the gaseous treatment process during the gas and/or its reaction products desorb from the product until predetermined levels are reached. This may be performed within the chamber and/or in a separate room. This can also be referred to as air washes or air exchanges

Bioburden: The naturally occurring pathogenic contamination in the suspect product load prior to exposure to a microbiocidal process

Biological indicator (BI). A measured and calibrated number of microorganisms with high resistance to the mode of sterilization being monitored, placed in or on a carrier and packaged to maintain the integrity of the carrier and microorganisms. The microorganism count is known and is higher than the bioburden load to be sterilized. The BI is used to verify the microbial lethality of the process.

Chamber treatment. The process by which the reproductive mechanisms of microorganism are interrupted to prevent replication Automatic sequence of operating stages performed in the chamber.

References

- FDA GMP/Quality System Regulation – CFR21 Part 110
- IFTPS -Protocol for Carrying out Heat Penetration Studies (Gas, Steam)
- IFTPS -Temperature Distribution Protocol for Processing in Steam Still Retorts, Excluding Crateless Retorts (Steam)
- ASTM Standards & Literature (Gamma)

Benefits

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

Hammer Award

January 19th 2001

- Teams who create an innovative and unique process or program to make government work better
- Teams who have shown large impacts on customer service, bottom-line results, streamlining government, saving money
- Exemplary achievements in government problem-solving.
- Effective and creative examples of government at its best.

Submission Recommendation

- Submitted to local District Office
- Attach a copy of the Protocol
- Completed Validation Form - Appendix III
- Include all supporting documentation
- Mock up of Reconditioning Form
- Provide personnel resumes to the District contact

Questions ?