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

CHAMBER TREATMENT

E.g. Ethylene Oxide and Propylene Oxide

Published and Prepared by

The American Spice Trade Association

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Table of Contents

1. Introduction

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.

2. Scope

a. This document applies specifically to the reconditioning of spices and culinary herbs which are either known or suspected to be contaminated with pathogenic microorganisms.
b. Products covered by this Protocol are listed in the American Spice Trade Association list of Spices and Culinary Herbs, and products listed in 21 CFR 182.10 Spices and other natural seasonings and flavorings. (Appendices I & II).
c. Infective vegetative pathogens are referred to as pathogens and/or pathogenic microorganisms throughout this document.
d. Chamber treatment, utilizing either ethylene oxide or propylene oxide, is the microbiocidal process for which this document is intended.
e. This document does not address occupational safety issues in the design or operation of the process equipment.
f. Pesticide regulations enforced by the U.S. Environmental Protection Agency are not within the scope of this document.
g. The terminology and definitions provided in Appendix V are not intended for use outside of this Scope.

3. General Provisions

a. Personnel
    i. Personnel with appropriate qualifications, experience and documented training perform the functions required by this guideline.
    ii. Chamber treatment specialists are involved in the design of systems and the development of the process.
b. Equipment is suitable for the intended purpose.
    General
        1. Steam supply additives, if used, are approved and suitable for food processes.
        2. If cross-contamination of pathogenic microorganisms from un-processed loads may occur within the chamber, bacterial retentive filters, no greater than 0.3 micron, are used on air inbleed lines.
        3. The chamber is intact and has a known leak rate.
        4. Gas and/or the vaporizer temperatures are continuously monitored while gas is injected. Appropriate controls are engineered to assure that gas temperature is achieved prior to discharge from vaporizer. Liquid gas is prevented from entering the treatment chamber.
        5. Process gases are within documented specifications for purity.
        6. Measurement and recording equipment are calibrated traceable to a national or international standard and the error is known.
        7. Gas is stored in a location and manner to prevent deterioration and contamination. Gas is used prior to the expiration date if one is provided by the supplier.
        8. The equipment is evaluated prior to use to insure that the design and operation of the chamber will provide the developed process.
c. The following information is provided on the monitoring records for each phase of the process, as required.
    i. Time
    ii. Temperature
        Chamber temperature
        Product temperature
    iii. Gas
        1. The quantity of gas.

2. Designate the system used in the determination of gas quantity i.e. pressure, weight, calculated concentration, or concentration by direct analysis.

iv. Relative humidity if direct steam inject is used. Direct analysis is the preferred method for recording relative humidity. However, due to the difficulty of acquiring accurate and reliable measurements of RH in an ethylene oxide environment, correlation of relative humidity to pressure rise and temperature is acceptable.

v. Pressure change from process gases.
   1. Gas
   2. Diluent, if used
   3. Steam, if used. This value relates to relative humidity
   4. Air

vi. An indication that the gas circulation system is operating, if used, e.g. paddle switch

d. Process Validation

i. Validation plan
   1. Two (2) or more microbiological performance studies are performed at the worst-case conditions for process lethality.
   2. The resistance and number of the surrogate organism must be selected to equal or exceed the treatment needed to destroy the target pathogenic microorganism of concern. The influence of the food to be treated needs to be considered.
   3. The chosen surrogate organism is appropriate and safe for use in a food process.
   4. The locations of the surrogate organism test strip or equivalent include the worst-cases for process conditions, including temperature, humidity (if used), and gas concentration.

      The worst case location for temperature is determined by performing temperature distribution studies of representative chamber loads. Sufficient temperature sensors are placed in the load to ensure that the coldest location is represented.
   5. If the worst-case location for temperature is not known, sufficient samples are used to ensure that the worst-case location is represented. To accomplish this, surrogate organism test strip or equivalent are distributed across the entire load. Emphasis on locations suspected to be worst case, for example near the chamber door, should be considered.
   6. If multiple products are treated in the same load, the impact of the mixture is evaluated.
   7. Variations in product packaging and unit package size are considered.
   8. Assuming performance equivalence between chambers is documented, it is acceptable to validate one chamber. In cases where a worst case chamber can be identified, that chamber should be used for the validation activities.

ii. See Appendix III for validation documentation and criteria for submission to FDA

e. Reconditioning Documentation and criteria for submission to FDA

i. See Appendix IV for documentation and submission requirements for reconditioned product. After reconditioning complete the form in Appendix IV and attach to an approved FDA Form766 Reconditioning Request Form (or equivalent) and submit to the FDA district office where the entry was made.

ii. Resume for the personnel performing the treatment, which include educational background, training, and qualifications to perform the treatment. This information will only need to be submitted once, unless changes in personnel occur. This information should be submitted to the FDA district office where the reconditioning site is located

4. Resubmission requirements

a. Changes to product, process, packaging and equipment are evaluated for their impact on the validated process. Re-validation is a possible result of this review.
b. Whenever the processing equipment, product, or the processing conditions/parameters are changed in a manner that may impact the safety and treatment effectiveness, revalidation of the process and resubmission of Appendix III are required.
c. If changes do not impact product safety, resubmission is not required. Support for the lack of impact must be on file at the site.
d. The purpose statement of the original validation submission is modified to identify the reason for resubmission.

5. Appendices

a. I. ASTA Approved Spice List
b. II. 21CFR**182**.**10** Spices and other natural seasonings and flavorings
c. III. Validation Submission Form
d. IV. Reconditioning Submission Form
e. V. Terminology Document
f. VI. US FDA Form 766, Web Address http://forms.psc.gov/forms/FDA/fda.html

6. References

a. FDA GMP/Quality System Regulation – CFR21 Part 110
b. IFTPS
Protocol for Carrying out Heat Penetration Studies

Appendix I & II

AMERICAN SPICE TRADE ASSOCIATION, INC.
SPICE LIST

Spices

ASTA recommends that for the purpose of complying with FDA food labeling regulations (21 CFR Sec. 101.22), the following items may be declared in a product's ingredient statement either individually by its common or usual name or included under the term "spice" as permitted in 21 CFR Sec. 101.22(h). The spices on this list, and their derivatives (e.g. extracts and oleoresins), are considered by FDA to be generally recognized as safe (GRAS), or approved food additives (See 21 CFR Secs. 172.510, 182.10, and 182.20).

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Allspice (Pimento)	Berry	Pimenta officinalis
Anise Seed	Seed	Pimpinella anisum
Star Anise	Fruit	Illicium verum Hook
Balm (lemon balm)	Leaf	Melissa officinalis L.
Basil Leaves (Sweet)	Leaf	Ocimum basilicum
Bay Leaves (Laurel Leaves)	Leaf	Laurus nobilis
Black Caraway (Russian Caraway Black Cumin)	Seed	Nigella sativa
Camomile, English or Roman	Flower	Anthemis nobilis L.
Camomile, German or Hungarian	Flower	Matricaria chamomilla L.
Capsicums	Fruit	Capsicum spp.
Caraway Seed	Seed	Carum carvi Maton.
Cardamom[1]	Fruit	Elettaria cardamomum
Cassia/Cinnamon	Bark	Cinnamomum spp.
Celery Seed	Seed	Apium graveolens
Chervil	Leaf	Anthriscus cerefolium
Chives	Leaf	Allium schoenoprasum
Cilantro (Coriander Leaf)	Leaf	Coriandrum sativum
Cinnamon/Cassia	Bark	Cinnamomum spp.
Cloves	Bud	Syzygium aromaticum
Coriander Seed	Seed	Coriandrum sativum
Cumin Seed (Cummin)	Seed	Cuminum cyminum
Dill Seed	Seed	Anethum graveolens/Anethum sowa
Dill Weed	Leaf	Anethum graveolens/Anethum sowa
Fennel Seed	Seed	Foeniculum vulgare
Fenugreek Seed (Foenugreek Seed)	Seed	Trigonella foenum-graecum
Galangal	Root	Alpinia officinarum Hance
Ginger	Root	Zingiber officinale
Horseradish	Root	Armoracia lapathfolia Gilib.
Juniper	Berry	Juniperus communis
Lavender	Flower	Lavandula officinalis Chaix.
Mace	Aril	Myristica fragrans
Marjoram Leaves	Leaf	Majorana hortensis Moench
Mustard Seed	Seed	Brassica juncea/B. hirta/B. nigra
Nutmeg	Seed	Myristica fragrans
Oregano Leaves	Leaf	Origanum vulgare/Lippia spp.

Paprika	Fruit	Capsicum spp.
Parsley (Dehydrated Parsley, Parsley Flakes)	Leaf	Petroselinum crispum
Black Pepper	Berry	Piper nigrum
White Pepper	Berry	Piper nigrum
Green Peppercorns	Berry	Piper nigrum
Pink Peppercorns	Berry	Schinus terebinthifolius
Peppermint Leaves (Peppermint Flakes)	Leaf	Mentha piperita
Poppy Seed	Seed	Papaver somniferum
Rosemary Leaves	Leaf	Rosmarinus officinalis
Sage Leaves	Leaf	Salvia officinalis/Salvia triloba
Savory Leaves	Leaf	Satureia montana/Satureia hortensis
Sesame Seed[1]	Seed	Sesamum indicum
Spearmint Leaves (Spearmint Flakes)	Leaf	Mentha spicata
Tarragon Leaves	Leaf	Artemisia dracunculus
Thyme Leaves	Leaf	Thymus vulgaris/Thymus serpyllum/Thymus satureioides
Vanilla Bean	Fruit	Vanilla planifolia/Vanilla tahitensis Moore

Dehydrated Vegetables Used As Spices

Because, in addition to their use as spices (e.g. granulated or powdered onion and garlic), these items are traditionally regarded as foods, they shall be declared by common or usual name consistent with 21 CFR Sec. 101.22(a)(2):

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Garlic	Bulb	Allium sativum
Onion	Bulb	Allium cepa

Spices Used As Color Additives

Consistent with 21 CFR Sec. 101.22(a)(2), the following spices, which can be used to impart color as well as flavor, shall be declared as "spice and coloring" or declared individually by common or usual name:

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Annatto Seed	Seed	Bixa orellana
Paprika	Fruit	Capsicum spp.
Saffron	Stigma	Crocus sativus
Turmeric	Root	Curcuma longa

FOOTNOTE:
[1]Must be listed by specific form (i.e., natural or hulled).

Revised April 2012
Approved by ASTA Board of Directors/Government Relations Committee April 2012

Appendix III
Chamber Treatment of Vegetative Pathogens
Process Validation Submission

This form should be completed by the reconditioner and include protocols and data collected during the validation of the chamber treatment process. The reconditioner should submit the form with attachments to the FDA district office where the reconditioning site is located. Each attachment must be labeled with the corresponding section and question numbers.

The submitter must demonstrate that, under specified controlled conditions, the process will consistently deliver at least the minimum lethality needed to effectively control the target pathogen(s) in the spice product(s) identified in the submission.

A copy of the validation protocol used by the reconditioner should be attached to this process validation submission.

I. Purpose

a. Describe the general purpose of this study including target organisms and spices :

II. Identification

a. Validation Date:	Validation ID:
b. Is this the initial submission for the process? (circle one) YES or NO **If NO**, is this a resubmission due to a change in: □ product □ process □ packaging □ equipment Provide previous validation date and ID below.	
c. Previous Validation Date:	Previous Validation ID:
d. Does this submission apply to more than one reconditioning facility? (circle one) YES or NO **If YES**, the preparer of this form need only submit one completed form to the nearest FDA district office. List the facilities covered by this submission. For each, identify the FDA district office with oversight authority:	

e. Specifically identify the treatment chambers covered by this validation study. If more than one chamber is covered, specify which chamber was used for the validation study and why that chamber was chosen:
f. List products covered by this validation:
g. Describe packaging (e.g., polywoven, burlap)covered by this validation:

III. Identify facilities and equipment covered by this validation. Provide responsible contact at each facility. Attach data from additional facilities.

a. Facility 1 Name:	Facility 2 Name:	Facility 3 Name:
b. Address:	Address:	Address:
c. Phone:	Phone:	Phone:
d. Fax:	Fax:	Fax:
e. Contact Name:	Contact Name:	Contact Name:
f. Email Address:	Email Address:	Email Address:
g. Validated Equipment ID(s):	Validated Equipment ID(s):	Validated Equipment ID(s):

IV. Company validation contact. Please provide the name(s) of the individual(s) responsible for designing and conducting the validation study.

a. Name:	Name:	Name:
b. Title:	Title:	Title:
c. Address:	Address:	Address:
d. Phone:	Phone:	Phone:
e. Fax:	Fax:	Fax:
f. Email Address:	Email Address:	Email Address:

V. Surrogate organisms

a. Identify the surrogate organism (the resistance and number of the surrogate must be selected in order to equal or exceed the treatment needed to destroy the target pathogenic microorganism of concern, e.g. Salmonella):
b. Provide an explanation for the choice of the surrogate.
c. Provide an explanation of the relationship between destruction of the surrogate organism and the target organism. Cite the reference for the D-values.
d. Provide concentration of surrogate organism used in validation studies.
e. Describe placement of surrogate organisms in the validation load (attach diagrams and/or maps).

VI. Bioburden of pathogenic microorganism

a. Results of bioburden testing (or literature reference search). Describe product bioburden level. Cite 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. This is to include discussion of gas concentration, temperatures (product and chamber), humidity, time etc.
b. If more than one chamber is covered, specify which chamber was used for the validation study and state why that chamber is worst case:
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., density, 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.
e. If different conditions are deemed worst case for different products etc. explain the rationale.

VIII. Loading conditions

a. Provide a description of the validated worst-case loading pattern, stacking configuration, and product density. Attach diagrams as appropriate.
b. Identify the worst-case location impacting process lethality, including temperature, gas concentration, etc.
c. If the load represents a worst-case for multiple loading configurations, describe the rationale used to select this configuration.

IX. Pre and post-processing conditions

a. Provide a description with tolerances of any pre-conditioning process that impacts the lethality of the process.
b. Provide a description with tolerances of any post-conditioning process that impacts the lethality of the process.

X. Effect of treatment conditions

a. Explain how the validation processing conditions relate to the normal processing conditions. Tables are an appropriate presentation form.

XI. Gaseous process

a. Specify type and brand of treatment chamber. Provide a physical description of the chamber and critical systems. Attach diagrams.
b. Identify gas type and blend:
c. Describe how weight or concentration of gas was determined (include calculation example).

XII. Study results

a. Provide a summary of test results for microbiological performance in cases where the surrogate organism is placed throughout the load (e.g. biological indicator placed in each pallet, chamber fully loaded). If surrogates are not placed throughout load, then provide temperature distribution data for loaded chamber and microbiological performance data. A minimum of two (2) studies should be performed Attach tables and reports from testing as appropriate.
b. If more than two (2) studies were performed, how many studies were performed for this validation? Discuss rationale.

XIII. Monitoring Method

Complete this section for each validation
Describe monitoring devices used to monitor the process during validation and normal production.

a. Pressure

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Please circle one: Routine Validation Both					

b. Chamber temperature

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s).					
Please circle one: Routine Validation Both					

c. Product temperature

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s). Attach placement diagrams.					
Please circle one: Routine Validation Both					

d. Relative humidity (if used)

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s).					
Please circle one: Routine Validation Both					

e. Gas concentration (if used)

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s).					
Please circle one: Routine Validation Both					

f. Treatment gas weight (if used)

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Please circle one: Routine Validation Both					

g. Chart

Description	Manufacturer	Model
Please circle one: Routine Validation Both		

h. Controller(s) – monitoring devices for key processes

Description	Manufacturer	Model
Please circle one: Routine Validation Both		

i. Preconditioning temperature (if used)

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s).					
Please circle one: Routine Validation Both					

j. Preconditioning relative humidity (if used)

Description	Manufacturer	Model	Range	Accuracy	Calibration Date & Calibration Reference I.D.
Quantity and location(s).					
Please circle one: Routine Validation Both					

k. Preconditioning recorder (if used)

Description	Manufacturer	Model
Please circle one:	Routine	Validation Both

l. Preconditioning controller (if used)

Description	Manufacturer	Model
Please circle one:	Routine	Validation Both

m. Additional equipment

List additional equipment that is critical to monitoring the validation or routine product of the process. Attach description and performance specifications.

n. Biological verification testing for routine reconditioning (optional)

Description. If samples such as biological indicators are routinely used to confirm the process effectiveness, attach placement diagrams.
Please circle one: Routine Validation Both

o. Reconditioning Monitoring Record

List reconditioning monitoring records. Attach sample record(s).

XIV. Process parameters.

For each phase in the process describe the worst case condition observed during the validation. Indicate the validated tolerance that this establishes for the reconditioning process. For example, if the product temperature observed prior to processing ranged between 45 – 48 º F then the Observed Worst Case is "45 º F" and the Validated Tolerance is ">45º F." Another example regarding gas concentration: if the gas concentration ranges from 250 – 300 mg/l then the Observed Worst Case is "300 mg/l" and the Validated Tolerance is ">300 mg/l."

All tolerances are to be stated as minimum or maximum values along with the appropriate unit of measure.

Parameter	Observed Worst-Case During Validation	Validated Tolerance	Operating Limit
Product temperature prior to processing			

Preconditioner (if used)			
Parameter	**Observed Worst-Case During Validation**	**Validated Tolerance**	**Operating Limit**
Preconditioning time			
Preconditioning temperature			
Preconditioning RH			
Transfer time from preconditioning (if used)			

Treatment Chamber			
Parameter	**Observed Worst-Case During Validation**	**Validated Tolerance**	**Operating Limit**
Treatment gas concentration			
Treatment gas weight			
Treatment dwell temperature			
Treatment dwell time			
Product temperature (if used)			
Chamber temperature			
Relative humidity (if used)			

Other Parameters			
Parameter	**Observed Worst-Case During Validation**	**Validated Tolerance**	**Operating Limit**

XV. Attach a blank steam reconditioning submission form (Appendix IV) and based on the validation insert the validated tolerance for processing condition parameters.

Signature of Company Validation Contact : _____Date _____

Appendix IV
Chamber Treatment of Vegetative Pathogens
Reconditioning Submission

This form should be completed by the spice firm for each reconditioning run and attach it to a copy of an approved Form FDA-766, Reconditioning Request Form or equivalent. The validation for this process and product must already be completed by the reconditioning firm and approved by the FDA prior to submitting this form. After processing, the spice firm submits the forms with any attachments to the FDA district office where the product made entry. Appropriate identification by section and question number is required for all attachments.

I. Product Identification

a. Entry Number (if applicable):
b. List product(s) to be reconditioned:
c. Describe product packaging:
d. Provide quantity of pieces and describe loading configuration. Attach diagrams if necessary:
e. Corresponding Validation ID:
f. Validation Date:

II. Reconditioning Facility and Equipment

a. Facility Name:
b. Address:
c. Phone:
d. Fax:
e. Contact Name:
f. Email Address:
g. Reconditioning Chamber ID:

III. Process Summary

a. Treatment Date:
b. Batch or Run #:

Process Conditions (all critical parameters per validation) Validated tolerances must state whether they are minimum or maximum values and list the unit of measure.

Parameter	**Observed**	**Validated Tolerance**
Product temperature prior to processing		

Preconditioner (if used)		
Parameter	**Observed**	**Validated Tolerance**
Preconditioning time		
Preconditioning temperature		
Preconditioning RH		
Transfer time from preconditioning (if used)		

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

IV. Corrective Action

a. Did the reconditioning process meet the validated tolerances? (circle one) YES or NO
b. If NO, describe corrective action(s) taken. Provide attachments, if necessary.

Signature of Reconditioner _____Date _____

Signature of Importer _____ _Date _____

Appendix V

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

TERMINOLOGY

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1. This document provides terminology for use with the guidelines for validation and routine production of microbiocidal processes for the control of pathogen contamination published by the American Spice Trade Association.

2. Scope
    a. This terminology is intended for use with the ASTA guidelines for steam, ethylene oxide, propylene oxide, and gamma irradiation of Spices and Culinary Herbs to eliminate pathogen contamination.
    b. The terminology and definitions provided are not intended for use outside of this scope.

3. Terminology
    a. **Absorbed Dose:** Quantity of radiation energy imparted per unit mass of matter. The unit of absorbed dose is the gray (Gy) where 1 gray is equivalent to absorption of 1 joule per kilogram (= 100 rads).

    b. **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.

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

    d. **Biological indicator (BI):** A measured and calibrated number of microorganisms with high resistance to the mode of treatment 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 treated. The BI is used to verify the microbial lethality of the process.

    e. **Chamber:** Enclosed area that accommodates the product to be treated. In case of ETO it is a pressured chamber, for irradiation it is at ambient.

    f. **Culinary Herbs:** See *ASTA Approved Spice List* and *Spices and Other Natural Seasonings* (21 CFR 182.10).). Appendix I & II

    g. **Dose Mapping:** Measurement of absorbed-dose within a process load using dosimeters placed at specified locations to produce a one, two or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

    h. **Dosimetry:** For Gamma Irradiation, the measurement of absorbed dose by the use of dosimeters.

    i. **Dosimetry System:** A system used for determining absorbed dose consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

    j. **Dosimeter:** Device or system having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given material.

    k. **D_{10} value:** Exposure time required under a defined set of conditions to cause a 1-logarithm or 90% reduction in the population of a particular microorganism. For calculation purposes it is assumed that the killing rate follows first-order kinetics.

    l. **F value:** Measure of the microbiological lethality of a process.

    m. **Irradiation (Gamma):** Gamma radiation from Cobalt 60 or Cesium 137.

    n. **Lethality:** *(Integrated Lethality)* - For Steam Treatment, the microbial destruction is defined in terms of F values where F equals the number of minutes needed to destroy a given number of organisms at a stated temperature.

o. **Pathogen:** Infectious, vegetative, a non-spore forming, food borne microorganism which is recognized as a public health hazard that can cause illness or death in humans. Principle pathogen in Spices is *Salmonella spp.*

p. **Pre-cleaning:** The removal of foreign material, e.g., organic or inorganic contaminants such as twigs, soil, grass or other discard plant material), from spices prior to a decontamination, disinfection, or treatment process.

q. **Preconditioning:** Treatment of product prior to the microbial reduction cycle in a room or chamber to attain specified limits for temperature and relative humidity. (See also conditioning)

r. **Pressure (absolute):** Pressure is referred to in absolute terms with no reference to barometric pressure. A complete vacuum in an absolute system is known as 0 pressure. The pressure measured when the reference baseline is 0 and not atmospheric pressure. For example, gauge pressure uses atmospheric pressure as a reference point and pressures are measured relative to the atmosphere.

s. **Process Load: A** volume of material with a specified loading configuration irradiated as a single entity.

t. **Residue:** The treatment agent or by-products of gaseous treatment remaining after completion of the treatment process, e.g., EtO or PPO

u. Reconditioning: The processing of contaminated spice to destroy infectious vegetative pathogens.

v. **Saturated steam:** The steam vapor (gas) pressure is at the saturation value according to standard saturated steam tables. The steam can not hold any additional vapor (gas). This is sometimes referred to as "wet" steam.

w. **Spices: :** See *ASTA Approved Spice List* and *Spices and Other Natural Seasonings* (21 CFR 182.10). Appendix I & II

x. **Sterilant:** The active agent(s) that achieves microbial reduction, e.g., EtO, PPO.

y. **Superheated steam:** The steam can hold additional vapor. The vapor pressure has not reached saturation. This is sometimes referred to as "dry" steam.

z. Surrogate organisms: A non-pathogenic microorganism chosen for the validated study that exhibits destruction characteristics similar to the pathogen of concern.

aa. **Treatment:** The process by which the reproductive mechanisms of microorganism are interrupted to prevent replication Automatic sequence of operating stages.

bb. **Validation:** Documented, scientifically based procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications.

cc. **Vessel:** Enclosed area that holds the product during steam treatment.

Treatment Validation References **Distributed October 23, 2002**

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