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

STEAM TREATMENT

Published and Prepared by

The American Spice Trade Association

September 10, 2001

Table of Contents

1. **Introduction**

This document is intended to be an informative reference for the practitioner of steam 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 flavoring. (Appendices I & II.)
c. Infective vegetative pathogens are referred to as pathogens and/or pathogenic microorganisms throughout this document.
d. Steam treatment 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. 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. Steam 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. Systems are typically closed and consist of a pressurized vessel and dryer
3. Systems are designed to prevent cross-contamination between processed and unprocessed materials. If air filters are employed to filter air inside the processing vessel, the filters are to be bacterial retentive filters, no greater than 0.3 micron
4. Process must specify type of steam saturated or superheated
5. Appropriate controls are engineered to assure that processing parameters are met.
6. Monitoring devices are located at appropriate sites.
7. Measurement and recording equipment are calibrated traceable to a national or international standard and the error is known.
8. The equipment is evaluated prior to use to insure that the design and operation of the steam 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
        1. Vessel temperature
        2. Dryer Temperature
    iii. Pressure
        Vessel Pressure

d. Process Validation –Either option is acceptable
    i. Time/Temperature method (integrated lethality)
        1. A sufficient number of calibrated test probes are installed at various locations in the steam environment surrounding the product load during temperature distribution testing.
        2. Two or more temperature distribution tests are performed to assure adequate venting of the vessel and to identify the zone (cold spot) which takes the longest to reach process temperature. For example on systems utilizing conveyor belts, this cold spot may be a lane position. The cold spot is normally performed under worst case conditions with the vessel being empty. The testing also needs to evaluate the vessel after venting under maximum loading conditions. Also, if cooling or drying contribute to process lethality, the fastest cooling or drying zone is identified.
        3. Heat penetration tests are then conducted in the slowest heating point in the product located in the slowest heating zone of the vessel.
        4. A sufficient number of heat penetration test units are studied at the slowest heating point within the slowest heating product to be treated. Factors to consider include product clumping tendency, accumulation of product. If cooling or drying lethality is credited, a sufficient number of test units are studied.
        5. The lethality from the slowest heating unit is quantified. If the cooling or drying lethality is credited, the test unit representing the fastest cooling is combined with the data from the slowest heating to establish the lethality value (F) of the process.
        6. Lethality calculations are performed to establish processing parameters - initial product temperature, process temperature, process time (considering conveyor speed), product considerations (e.g., maximum thickness) and conveyor speed. See Appendix VII for calculations.
    ii. Validation by Microbial performance will consist of
        1. Two or more microbiological challenge studies or bio-reduction studies are performed at the worst-case conditions for process lethality.
        2. The resistance and number of the surrogate organism must be selected in order to equal or exceed the treatment needed to destroy the target pathogenic microorganism of concern.
        3. The chosen surrogate organism is appropriate and safe for use in a food process
        4. The influence of the food to be treated needs to be considered.
        5. The locations of the surrogate organism samples include the worst-cases for process conditions, including temperature, pressure and time.
        6. If multiple products are treated in the same load, the impact of the mixture is evaluated.
        7. Variations in products are considered.
    iii. See Appendix III for validation documentation and criteria for submission to FDA.

e. Reconditioning Documentation and Submission Requirements
    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 (Appendix VI) 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.

.

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. 21 CFR 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
g. VII. Lethality Calculations

6. References

a. FDA GMP/Quality System Regulation – 21 CFR Part 110
b. IFTPS
    i. Protocol for Carrying out Heat Penetration Studies
    ii. Temperature Distribution Protocol for Processing in Steam Still Retorts, Excluding Crateless Retorts.

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
Steam Treatment of Vegetative Pathogens
Process Validation Submission Form

This form should be completed by the reconditioner and include protocols and data collected during the validation of the steam 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 protocol used for validation 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 vessels covered by this validation study:
f. List products covered by this validation:
g. Is the product treated in the packaging or not?

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 (COMPLETE THIS SECTION IF VALIDATION IS BASED ON MICROBIOLOGICAL CHALLENGE STUDY OR BIO-REDUCTION STUDY)

a. Identify the surrogate organism (the resistance and number of the surrogate organism 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 microbiological challenge studies or for bio-reduction studies, provide level of surrogate organism in the spice prior to treatment.
e. For microbiological challenge study, 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.
b. Is product treated in package (see Section II f), specify the type of packaging and why this 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, flowability (clumping), moisture content, antimicrobial properties, bioburden, penetration (heat), previous treatment

VIII. Through put rates

a. Provide a description of the validated worst-case loading conditions on conveyance system, e.g. product thickness on belt, characteristic of system influencing flow, etc.
b. Identify the worst-case location impacting process lethality, including temperature, cold spots etc.
c. If the load represents a worst-case bed thickness, describe the rationale used to select this thickness.

IX. Pre and post-processing conditions (if applicable)

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, e.g. drying after steam treatment

X. Steam process

a. Specify type and brand of treatment vessels (should include dryers if used for post-conditioning). Provide a physical description of the vessel and critical systems**. Attach diagrams**.
b. Direct or in-direct application of steam:

XI. Validation study results

a. Identify Validation type employed 1. Microbiological Challenge, 2. Bio-reduction Study, or 3. Time//Temperature Method (Integrated Lethality) .
b. Attach tables and reports from testing as appropriate. For bio-reduction studies, identify where pre and post treatment samples are collected.
c. If more than two (2) studies were performed, how many studies were performed for this validation? Discuss rationale. .

XII. 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. Vessel 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. Dwell Time dictated by design

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

e. Temperature recorder

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

f. Controller – monitoring devices for key processes

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

g. Post conditioning temperature (dryer), if applicable

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

h. Post conditioning recorder (dryer), if applicable

Description	Manufacturer	Model
Please circle one:	Routine	Validation Both

i. Post conditioning controller, if applicable

Description	Manufacturer	Model
Please circle one: Routine Validation Both		

j. Additional equipment

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

k. Reconditioning monitoring record

List reconditioning monitoring records. Attach sample record.

XIII. 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 observed validation temperatures vary between 220°F and 222°F, record 222°F as the observed worst case and ≥222°F as validated tolerance.

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**
Product temperature prior to processing		

Vessel		
Parameter	**Observed Worst-Case During Validation**	**Validated Tolerance**
Pressure		
Dwell Time		
Temperature		

Postconditioner (if used)		
Parameter	**Observed Worst-Case During Validation**	**Validated Tolerance**
Postconditioning time		
Postconditioning temperature		
Transfer time from steam treatment		

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

XIV. 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
Steam Treatment of Vegetative Pathogens
Reconditioning Submission Form

This form should be completed by the spice firm for each reconditioning run and attached 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 if product is treated in package:
d. Corresponding Validation ID:
e. Validation Date:

II. Reconditioning Facility and Equipment

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

Vessel		
Parameter	**Observed**	**Validated Tolerance**
Pressure		
Dwell Time		
Temperature		
Other parameter(s) as dictated by validation		

Post conditioner (e.g. drying), if applicable		
Parameter	**Observed**	**Validated Tolerance**
Post conditioning time		
Post conditioning temperature		
Transfer time from steam treatment		

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

Published and Prepared by
The American Spice Trade Association

September 10, 2001

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.

SUBMIT IN TRIPLICATE *(Submit in QUADRUPLICATE if you desire copy returned to you.)*

APPLICATION FOR AUTHORIZATION TO RELABEL OR TO PERFORM OTHER ACTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND OTHER RELATED ACTS

FORM APPROVED: OMB No. 0910-0025
EXPIRATION DATE: 7/31/2020

TO: DIRECTOR

_____ Division,
Food and Drug Administration

Application is hereby made for authorization to bring the merchandise below into compliance with the Act.

DATE	SAMPLE NO.
PRODUCT	
ENTRY NO.	ENTRY DATE

CARRIER	AMOUNT AND MARKS

Redelivery bond has been posted by the applicant. The merchandise will be kept apart from all other merchandise and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at:

_____ and will require

about _____ days to complete. A detailed description of the method by which the merchandise will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

FIRM NAME	ADDRESS OF FIRM
APPLICANT'S SIGNATURE	

ACTION ON APPLICATION

TO: *(Name and Address)*	DATE

Your application has been: ☐ Denied because: ☐ Approved with the following conditions:

Time limit within which to complete authorized operations: _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

SIGNATURE OF DIVISION DIRECTOR	DIVISION	DATE

IMPORTER'S CERTIFICATE

PLACE	DATE

I certify that the work to be performed under the authorization has been completed and the goods are now ready for inspection at: _____

_____.

The rejected portion is ready for destruction under Customs' supervision and is held at: _____

_____.

TYPED NAME OF APPLICANT	SIGNATURE

REPORT OF INVESTIGATOR / INSPECTOR

TO PORT DIRECTOR OR DIVISION DIRECTOR	DATE

I have examined the within-described goods and find them to be the identical goods described herein, and that they have been: _____ on: _____ , 20 ____ , as authorized, except:

DATA ON CLEANED GOODS

Good Portion:

Rejections:

Loss (if any):

Did importer clean entire shipment?

Time and cost of supervision:

INSPECTING OFFICER	DATE

DIVISION DIRECTOR

Disposed of as noted above.

DIRECTOR OF CUSTOMS	DATE

Appendix VII

Steam Treatment of Vegetative Pathogens
Lethality Calculation

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.

The Calculation is as follows

Lethal Rate = $\log^{-1}$ [(PT – RT)/z] OR 1/$\log^{-1}$ [(RT - PT)/z]

Process Temperature = PT
Reference Temperature = RT

An Excel Spreadsheet can be developed for the calculations as follows :

Assuming z=9 Ref = 158 degs/ F

	Time	ºF	
Heating	0	136	
Cell 2 (Time) - Cell 1 (Time) x $\log^{-1}$ [(PT-158)/z]	2	143	(2-0)*$\log^{-1}$[(143-158)/9] = 2(.0215) = 0.043
Cell 3 (Time) - Cell 2 (Time) x $\log^{-1}$ [(PT-158)/z]	4	149	(4-2)*$\log^{-1}$[(149-158)/9] = 2(.100) = 0.2
Cooling	6	147	(6-4)*$\log^{-1}$[(147-158)/9] = 2(.06) = 0.12

F_{158}^{9} = 0.363 minutes

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

Spices and Salmonella

Joseph CA, Mitchell EM, Cowden JM, Bruce JC, Threlfall EJ, Hine CE, Wallis R, Hall MLM. 1991. A national outbreak of salmonellosis from yeast flavoured products. CDR Review 1:R16-R19.

Juven BJ, Cox NA, Bailey JS, Thomson JE, Charles OW, Shutze JV. 1984. Survival of *Salmonella* in Dry Food and Feed. Journal of Food Protection 47(6):445-448.

Lehmacher A, Bockemuhl J, Aleksic S. 1995.Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. Epidemiology & Infection 115(3):501-511.

Gas Treatment – ETO & PPO

Himmelfarb P, El-Bisi HM, Read RB, Litsky W. 1962. Effect of Relative Humidity on the Bactericidal Activity of Propylene Oxide Vapor. Appl. Microbiol.10; 431-434.

Marrissey RF, Phillips GB. 1993. Sterilization Technology: A Practical Guide for Manufacturers and Users of Health Care Products. New York. Van Nostrand Reinhold.

Heat and Steam Treatment

IFTPS. 1995. Protocol for Carrying out Heat Penetration Studies. Fairfax, VA. The Institute for Thermal Processing Specialists. Available from IFTPS (IFTPS@juno.com). Nov. 1995.

IFTPS. 1992. Temperature Distribution for Processing in Steam Still Retorts, excluding crateless Retorts. Fairfax, VA. The Institute for Thermal Processing Specialists. Available from IFTPS (IFTPS@juno.com). Nov. 1992.

Irradiation

Eiss M. 1984. Irradiation of Spices and Herbs. Food Tech in Australia. 35(8):362-370.

EPS. 2000. Disinfection Technique could have Processors Beaming. Food Quality Jan-Feb 2000; 36-40.

Sharma A, Gautam S, Jadhav SS. 2000. Spice Extracts as Dose-Modifying Factors in Radiation Inactivation of Bacteria. J Agric Food Chem 48:1340-1344.

Thayer DW (editor) . 1996. Radiation Pasteurization of Food. Ames, IA. Council for Agricultural Science and Technology. Available from CAST (cast@cast-science.org). No. 7; April 1996.