

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

GAMMA IRRADIATION

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The American Spice Trade Association

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1. Introduction

a. General Information

- i. This document provides basic information concerning the use of ionizing radiation as a treatment process for the elimination of pathogenic microorganisms on spices and culinary herbs as defined in 21 CFR § 179.26.
- ii. Irradiation has been demonstrated to be effective in killing pathogenic organisms that may contaminate spices and culinary herbs. Farkas (1988), Narviaz et al. (1989) and IAEA (1992) have reviewed the effects of irradiation on spices and their reports are incorporated in this document by reference. The radiation dose requirement for spice treatment depends upon the number and types of microorganisms present as well as their relative resistance to ionizing radiation.
 1. The D₁₀ of salmonella has been reported to be 0.96 +/- 0.05 kGy in alfalfa sprout seeds as reported in: *Irradiation of Food Sprouts and Seeds*, D. W. Thayer, K.T. Rajkowski, et al, USDA ARS, NAA, ERRC, 600 East Mermaid Lane, Wyndmoor, PA 19038, March 2000.

b. Approved sources of radiation

The sources for energy commonly used in irradiation treatment are gamma-emitting isotopes (cobalt-60 or cesium-137). The source and equipment used for this treatment must be capable of safely and effectively irradiating the commodities to the specifications, which are required for the specific organism under the conditions of the treatment.

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. Gamma processing 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. Facility Requirements

- i. To be authorized, in general, approved facilities (USNRC approved or Agreement State Licensed) must be able to demonstrate to FDA that their equipment and personnel are able to accurately, and consistently deliver the minimum dose to all portions of the commodity over the range of packaging conditions expected for commodities treated. All facilities agree to immediately notify the importer of any problems, concerns, or irregularities in commodity treatments
- ii. Standard Operating Procedures (SOP's) shall be developed by each facility that utilizes irradiation of commodities for the elimination of pathogenic organisms. It must include the specific procedures for all facets of handling, safeguarding and treating the commodities. The document(s) will be reviewed and scrutinized along with the facility and personnel qualifications in determining the acceptability for use. The document(s) will be referenced as a part of a written agreement between the importer and the radiation processor.

b. Conditioning Components

Importers desiring irradiation reconditioning must follow the stipulations of 21 CFR 179.

- i. Spices treated with ionizing radiation shall receive the minimum radiation dose required to accomplish the intended technical effect, and not more than the maximum specified by 21 CFR 179.26 (b) (5).
- ii. Packaging materials shall comply with 21 CFR 179.45 or other applicable authorization.
- iii. Written procedures shall be implemented to ensure adequate commercial processing.
- iv. Qualified individuals shall operate a commercial processor.
- v. Records shall be maintained for a period of time that exceeds the shelf life of the irradiated spice by 1 year, up to a maximum of 3 years.

c. General Procedures

- i. The written agreement shall describe the pertinent procedures applicable to the particular facility.
 1. Packaging - Reference 4: 21 CFR 179.45, or other applicable authorization

2. Marking/labeling – as per CFR 179.26 (c)(3).
- ii. Treatment documentation
 1. The irradiation facility shall issue a Certificate of Irradiation to the importer (Appendix IV) for each batch (lot) treated. Key pieces of information to include are:
 - a. Name of product
 - b. Product Code No., if applicable
 - c. Description of product
 - d. Quantity of distinct units
 - e. Type of packaging unit (bags, boxes, drums, etc.)
 - f. Lot or batch identification
 - g. Date of irradiation
 - h. Minimum and maximum doses specified
 - i. Minimum and maximum doses delivered
 2. Maintain records of dosimetry system calibrations, as well as dosimeter batch calibration.
 3. Maintain dose mapping records
 4. For routine product processing, loading patterns shall be developed and maintained.
 5. Maintain records of all deviations from protocol (SOPs) and of corrections taken
- d. Process Validation
 - i. Dosimetry system. ASTM E1261, *Standard Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing*, is referenced as a guide for the selection of an appropriate routine dosimetry system that matches the absorbed dose requirements for the specific application criteria. Prior to use, the dosimetry system shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process, including traceability to national standards, and quality assurance requirements. This calibration shall be repeated as appropriate, to ensure that the minimum dose is given to the targeted organism(s).
 - ii. Dose Mapping. The irradiation facility shall perform sufficient dose mapping studies to fully characterize the distribution of dose in the irradiation container to determine the zones of minimum and maximum dose. Dose mapping activities shall be conducted with consideration of the density ranges of the commodities to be processed. Product loading patterns and pathway used for irradiation processing shall also be addressed. The information from the dose mapping studies is used in the selection of dose monitoring locations for routine product dosimetry. Additional dose mapping is required when significant changes are made to the irradiator, or to the process load, that could affect the distribution and/or quantity of absorbed dose. Dose mapping shall comply with ASTM E1204, *Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing*.
 - iii. See Appendix III for validation documentation and criteria for submission to FDA.
 - iv. ASTM F 1885 – 98, *Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms*, is referenced as a means of evaluating the processing system.
 - e. Routine Production Dosimetry

Ensure that the product receives the minimum designated absorbed dose for the targeted organism (see ASTM Standard E1204).
 - f. Record Keeping
 - i. The irradiation processor shall maintain treatment records in accordance with the provisions of 21 CFR 179. These records shall include the importer's lot (batch) identification, dosimetry records, ionizing energy source, dosimetry calibration records, dose mapping, and the date of irradiation. Records and bills of lading for each treated lot (batch) shall be available for inspection by designated regulatory officials.
 - ii. Documents regarding training

The training of key employees shall be properly and adequately documented. Such records shall be made available for inspection by designated regulatory officials.
 - g. Reconditioning Documentation and Submission Requirements
 - i. For each reconditioning run, the irradiation processor shall provide to the spice firm a completed Certificate of Irradiation. The spice firm will then attach the Certificate of Irradiation (Appendix IV) to an approved FDA Form 766 Reconditioning Request Form (or equivalent) and submit to the FDA district office where the entry was made.

- ii. Résumés for the personnel performing the treatment, which include educational background, training, and qualifications to perform the treatment, shall be maintained by the irradiation processor.

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, re-validation 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. Certificate of Irradiation Form
- e. V. Terminology Document
- f. VI. US FDA Form 766, Web address <http://forms.psc.gov/forms/FDA/fda.html>

6. References

- a. Farkas, J. (1988) *Irradiation of dry food ingredients*, CRC Press Inc., Boca Raton, Florida, pp. 11-40.
- b. IAEA (1992) *Irradiation of spices, Herbs and other Vegetable Seasonings - compilation of technical data for its authorization and control*, IAEA-TECHDOC-639, International Atomic Energy Agency, Vienna.
- c. Narviaz, P., Lescano, G., Kairiyama, E. and Kaupert, N. (1989) *Decontamination of spices by irradiation*, Journal of Food Safety, 10, 49-61.
- d. *Irradiation of Food Sprouts and Seeds*, D. W. Thayer, K.T. Rajkowski, et al, USDA ARS, NAA, ERRC, 600 East Mermaid Lane, Wyndmoor, PA 19038, March 2000.
- e. 21 CFR 179 – Food Irradiation (www.access.gpo.gov).
- f. ASTM F1885 – 98 *Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms*. (1998)
- g. ASTM E1204, *Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing*
- h. ASTM E1261, *Standard Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing*
- i. Title 10 – US NRC Radioisotope Materials License Regulations

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

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

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Appendix III

Gamma Irradiation Treatment of Vegetative Pathogens Process Validation Submission

Irradiation must be performed in compliance with the pertinent parts of 21 CFR 179.

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

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. Irradiation has been demonstrated to be effective in killing Salmonella in spice and culinary herbs (90% reduction for each kGy). If Salmonella is not the target organism for this process qualification, state the target organism(s) and provide the scientific basis for the selection of the minimum absorbed dose needed to effectively control this target pathogen. This requirement may be satisfied by providing relevant literature citations and available published references.

b. State the spices and/or culinary herbs covered by this validation:

II. Identification

a. Validation Date:
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: <input type="checkbox"/> product <input type="checkbox"/> process <input type="checkbox"/> packaging <input type="checkbox"/> equipment Provide previous validation date below.
c. Previous Validation Date:
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 irradiators covered by this process validation. Include the facility characterizations, the facility diagrams, irradiation paths, source configurations, and source strengths on date of submission of this document:

III. Provide responsible contact at each facility.

a. Facility 1 Name:	Facility 2 Name:	Facility 3 Name:
b. Address:	Address:	Address:
c. Contact Title	Contact Title	Contact Title
d. Fax:	Fax:	Fax:
e. Phone:	Phone:	Phone:
f. Email Address: (if applicable)	Email Address: (if applicable)	Email Address: (if applicable)

IV. Establishing dosimetry and dose mapping procedures

a. Describe dosimetry systems. Include measurement uncertainties associated with absorbed-dose measurements for each dosimetry system (See ASTM E1707- Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing) :

b. Describe calibration of dosimetry systems:

c. Describe dose mapping procedures:

i. Describe dosimeter placement schemes:

ii. Provide the basis for selection of dosimeter locations and the number of dosimeters per set:

iii. Describe any additional dose map requirements:

V. Other relevant Comments

NOTE: For each reconditioning run, the reconditioner shall provide to the spice firm a Certificate of Irradiation (Appendix IV). The spice firm will then attach the Certificate of Irradiation to an approved Form FDA-766 Reconditioning Request Form (or equivalent) and submit them to the FDA district office where the entry was made.

Signature of Preparer: _____ Date _____

Phone: _____ Fax: _____ email: _____

Appendix IV

CERTIFICATE OF IRRADIATION PROCESSING

For each reconditioning run, the reconditioner shall provide to the spice firm a completed Certificate of Irradiation. The spice firm will then attach the Certificate of Irradiation (Appendix IV) to an approved FDA Form 766 Reconditioning Request Form (or equivalent) and submit to the FDA district office where the entry was made.

Company Name & Location:				
Customer Name:				
Customer P.O.:				
Entry Number <i>(same as entry number on FDA 766 reconditioning application):</i>				
Irradiation Run Number/Lot Number:				
Irradiation time and date:				
Prod. Code No.	Prod. Lot No.	Description	Qty	Type Pack
Comments:				
Minimum Specified Dose:			Minimum Delivered Dose:	
Maximum Specified Dose:			Maximum Delivered Dose:	

APPROVED: _____

Title: _____ **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

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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. **D₁₀ 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.

Spices and Salmonella

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