



The Expert Voice of the U.S. Spice Industry in the Global Market

Updated ASTA Guidance on Science-Based Groupings to Optimize Validation of Spice Process Controls





Objectives of Today's Webinar

- ❑ Discuss the latest ASTA guidance on validation of spice treatment processes
 - Research on surrogate organisms for use in spice process controls
 - Science-based approach to validate a “worst case” representative product of a group of spices
 - Impact of microbial inhibition of spices on validation studies
- ❑ Review FSMA requirements and enforcement environment
- ❑ Get an overview of ASTA's resources and guidance on validation



Agenda

- Introduction & Background
- Regulatory Requirements Review and Updates
- Updated Guidance on Science-Based Groupings to Optimize Validation of Spice Process Controls
- Examples
- Questions & Discussion





Introduction & Background

Enabling food safety is one of ASTA's key strategic goals



ASTA Resources on Validation



Guidance

- ASTA White Paper on Process Validation
- Guidance on Science-Based Groupings to Optimize Validation of Spice Process Controls
- ASTA General Protocols for the Validation of Microbiocidal Processes on Pathogen Contaminated Spices and Culinary Herbs (a. CHAMBER TREATMENT b. GAMMA IRRADIATION c. STEAM TREATMENT)

Recorded Webinars on Validation of Process Controls

- 3-part Validation of Process Controls Webinar Series
- ASTA Online 2020: Validation Information for Spice Companies presented by FDA
- ASTA Online 2021: Panel Discussion on Science-Based Groupings

Research

- Literature Review on Irradiation of Spices
- Evaluation of Antimicrobial Properties on the Surrogate Organism *Enterococcus faecium* for Validation of Spice Processing Controls
- ILSI Surrogate Irradiation Study 2019

Resources are available at <https://www.astaspice.org/food-safety-technical-guidance/microbial-safety/> & <https://www.astaspice.org/industry-news-events/webinars/update-asta-guidance-on-science-based-grouping-to-optimize-validation-of-spice-process-controls/validation-resources-for-webinar-attendees/> (passcode: Validation)

Additional ASTA Food Safety Resources



[Home](#) [About ASTA](#) [News & Events](#) [Programs & Resources](#) [Food Safety](#) [Advocacy & Regulations](#)

Food Safety & Technical Guidance

It is ASTA's mission to ensure the supply of pure, safe spice. ASTA and its members are dedicated to promoting the safety and integrity of the spice supply chain. Supporting public health and protecting consumers is ASTA's top priority.

ASTA provides a range of programs and publications and conducts research to ensure companies have the tools they need to meet that goal. The resources in this section are available free to members and many are also available free to non-members. There is a fee for access to educational recordings.



Not a member yet? Visit [about membership](#) to find out more about the benefits of membership and how to [join ASTA](#).

[Analytical Methods](#) - The official Analytical Methods Manual of the American Spice Trade Association is available to members and industry professionals. ASTA also published the Microscopic Identification of Spice Manual as a reference text for the microscopic or histological identification of pure spices.

[Adulteration and Contamination Prevention](#) - Adulteration and food fraud can pose serious issues for companies. The most common examples of economically motivated adulteration involve the addition of materials to make a food seem more valuable and while this is frequently not a safety issue, it is of concern to the entire food industry. A number of resources are available from ASTA and other organizations to address adulteration and food fraud.

[Microbial Safety](#) - Due to the environments in which they are grown, spices and herbs often harbor microorganisms, including bacteria. These include potential spoilage organisms and pathogens of public health significance. This page includes information about the presence of microbiological hazards on spices and the control and mitigation of these hazards. This includes information about the presence of microbiological hazards on spices and the control and mitigation of these hazards.

[Best Practices and Guidance](#) - ASTA publications ensure companies have the tools they need to meet the goal of safety and integrity of the spice supply chain. These resources in this section are available free to members and many are also available free to non-members. There is a fee for access to educational recordings available.

Microbial Safety

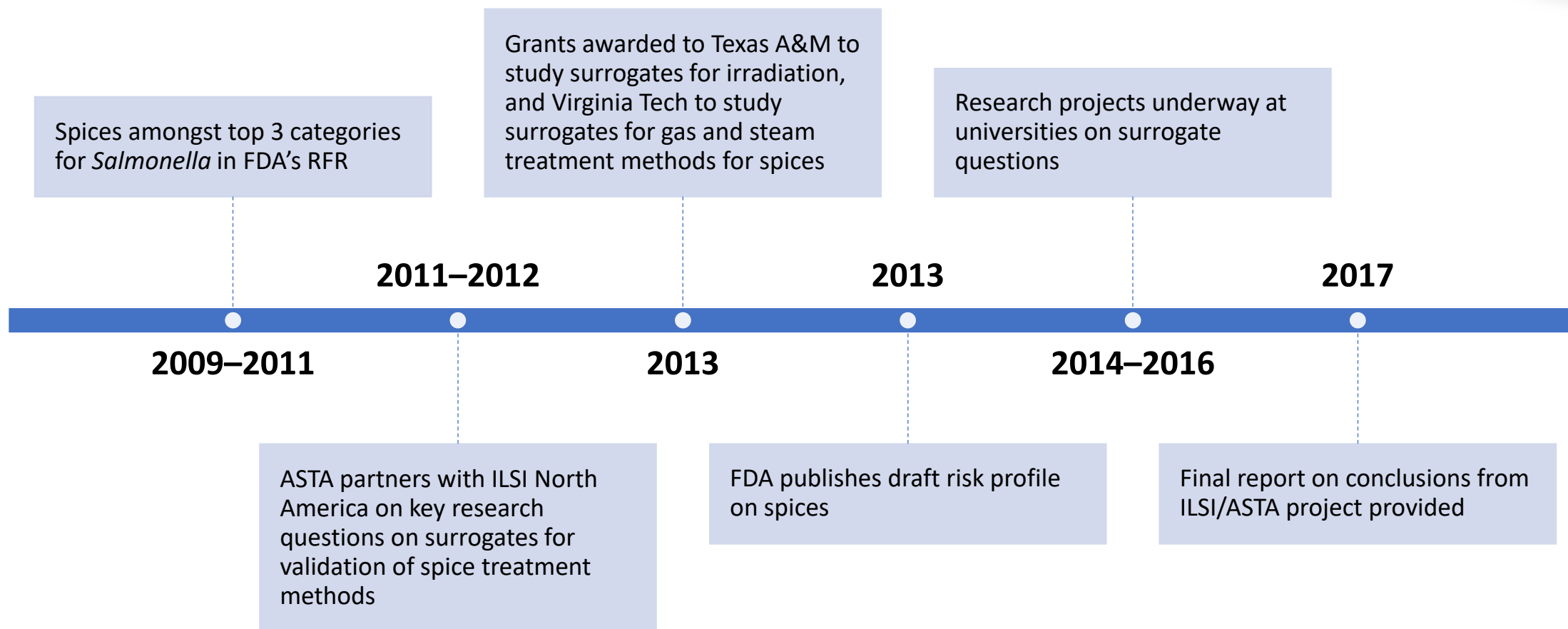
- [Microbiology of Spices White Paper](#);
- [Salmonella Detection Methods and Laboratory Best Practices for Seasonings, Herbs and Spice Matrices](#)
- [Webinar Series on the Microbiology of Spices](#)
- [Literature Review on Irradiation of Spices](#)
- [Developing a FSMA Ready Environmental Monitoring Program](#)
- [What Spice Companies Need to Know About the Presence and Control of Spore-forming Bacteria on Spice](#)

Food Safety Guidance Documents

- [Identification and Prevention of Adulteration Guidance Document](#);
- [Clean, Safe, Spices Guidance Document](#);
- [Cleanliness Specifications](#);
- [Good Agricultural Practices Guide \(GAP Guide\)](#);
- [Good Manufacturing Practice \(GMP\) Guide for Spices](#);
- [HACCP Guide to Spices and Seasonings](#);
- [Principles of Physical Cleaning Guide](#);
- [Environmental Monitoring](#)



Validation Surrogate Research Timeline





Key Research Conclusions

- *E. faecium* identified as surrogate for *Salmonella* in spice validation studies, but depends on spice, treatment, packaging, etc.
 - **Steam** - *E. faecium* was considered an equivalent surrogate for inactivation of *Salmonella* inoculated on peppercorns treated with steam, but not cumin seeds at temps < 165°F
 - **Gas** – EtO fumigation resulted in larger reductions in *Salmonella* vs *E. faecium* on whole black peppercorns and no significant difference in reduction on cumin seeds. Thus *E. faecium* is suitable as an equivalent surrogate for validating gas treatment methods.
 - **Irradiation** – *E. faecium* shown to be suitable surrogate for *Salmonella* in onion powder, dried oregano, whole cumin seeds or peppercorns treated with irradiation





Publications from this Research

- [Inactivation of *Salmonella enterica* and Surrogate *Enterococcus faecium* on Whole Black Peppercorns and Cumin Seeds Using Vacuum Steam Pasteurization](#)
- [Inactivation of *Salmonella enterica* and *Enterococcus faecium* NRRL B2354 on cumin seeds using gaseous ethylene oxide](#)
- [Identification of a surrogate to validate irradiation processing of selected spices](#)



FDA Meeting 2017



- ASTA met with FDA in 2017 to share results from the ILSI research
 - FDA raised concerns regarding the impact of microbial inhibition on the surrogate
 - During this meeting FDA confirmed that a specific validation study does not need to be conducted for each spice product
- ASTA has continued to have an open dialogue with FDA regarding these topics



Further Research on Impact of Microbial Inhibition on *E. Faecium*

- In 2018, ASTA conducted a benchtop study on spices with the highest degree of microbial inhibition*: cloves, cinnamon, allspice and oregano
- In these experiments, *E. faecium* was inhibited by all of the spices to the same degree, or less than, the five strains of non-typhoidal *Salmonella enterica* tested
- Combined with the previous research conducted by Virginia Tech and Texas A&M, this work provides strong support for the appropriateness for the use of *E. faecium* as a surrogate



*Billing and Sherman, 1998

Science-Based Approach to Groupings of Spices



- Since it is resource prohibitive to run a process control validation study on each individual spice, there is a need for a science-based approach to validate groupings of spices
- This entails running a study on a “worst case” representative product to validate an entire group
- To inform this science-based approach, ASTA formed a task force of ASTA members, worked with industry and academic experts, and held discussions with FDA
 - FDA presented to ASTA membership on this topic during ASTA Online 2020 and ASTA Online 2021





Regulatory Considerations for Validation

Maile Gradison

Partner, Hogan Lovells US LLP

maile.gradison@hoganlovells.com / 202-637-5428



Legal Framework – A Quick Refresher

- The Preventive Controls for Human Food (PCHF) rule requires a hazard analysis to be conducted to identify any hazards requiring preventive controls (HRPCs)
 - FDA's *PCHF Appendix 1 Draft Guidance* identifies *Salmonella* as a potential hazard for spices
- The PCHF rule requires that a preventive control be implemented to significantly minimize or prevent any HRPCs
 - The hazard of *Salmonella* is typically addressed with a process control – e.g., chemical treatment (ETO, PPO), steam treatment, or irradiation
- Process controls must be validated to confirm that they are effective

Requirements for Validation of Process Controls



- Who?
 - Validation must be performed or overseen by a Preventive Controls Qualified Individual (PCQI)
- What?
 - Validation must include “obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the PCs, when properly implemented, will effectively control the hazards.”
- When?
 - Prior to implementation of the Food Safety Plan (FSP), or, when necessary to demonstrate the control measures can be implemented as designed:
 - Within 90 calendar days after production of the applicable food begins, or
 - Within a reasonable timeframe, provided that the PCQI prepares (or oversees the preparation of) a written justification for the timeframe to exceed 90 days after production of the food first begins
 - Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of controls measures, when properly implemented, will effectively control the hazards
 - Whenever a reanalysis of the FSP reveals the need to do so
- Where?
 - Each facility covered by the PCHF rule needs validation for their process preventive controls. Industry studies can be leveraged, but you need to be sure that they fit your process.



Validation v. Verification

- Validation: If you follow this process, does it work to effectively control the hazard? Is this process capable of being properly implemented?
- Verification: Are you doing what you said you'd be doing? Is the process operating as intended?

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.



Validation Challenges

- Do you have to validate every spice individually?
 - No! This is where ASTA's work comes in.
 - FDA has advised ASTA that you can use groupings and rely on validation of “worst case scenarios” – i.e., only perform validation on one spice that is representative of an appropriate group
- Do you have to do this all on your own?
 - No! You can leverage ASTA's work, so long as you can demonstrate it fits with your own process and parameters



FDA Guidance

- FDA has stated that it intends to develop guidance on validation, but has not yet done so.
- Topics addressed may include commodity-specific guidance to help facilities understand what preventive controls are capable of being validated and to design testing to ensure validation conditions always exceed conditions during production.
- The best available guidance from FDA is from preamble statements in the PCHF proposed rule (78 Fed. Reg. 3646, 3753-54 (Jan. 16, 2013)).



FDA Guidance

- “If relying on sources such as scientific publications, ensure the conditions used by the facility are consistent with those described in the publication. For example, if a study demonstrates adequate inactivation of *Salmonella* spp. in peanuts using a roasting process, conditions such as roaster temperature, heating time, bed depth and humidity that were critical to achieving inactivation in the study must be the same when the facility roasts peanuts (or any change in the critical parameters must be such that the same or greater lethality is achieved).”
- “If a model for the thermal resistance of *Salmonella* spp. is developed in tomatoes with a pH of 4.3, the model would be valid for tomatoes with a pH of 4.3 or below, but not for tomatoes with a higher pH. If, however, the model is for a type of food that is only similar to the food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional thermal resistance studies in the food being produced to provide the data needed to show that a heat process adequately reduces *Salmonella* spp. in that food.”



FDA Enforcement Considerations

- Imports
 - FDA applies significant scrutiny to validation in the context of imports. If food is detained at entry, this means it is presumed to be adulterated. Reconditioning submissions must be strong enough to overcome this presumption.
 - Consequences: Import rejection; placement on Import Alert
- PCHF Inspections
 - Facility inspections tend to focus on only a few products. Inspectors may check for validation as a PCHF requirement, but they lack the technical expertise to truly scrutinize the strength of the data. If there are concerns, they will involve a subject-matter expert from CFSAN.
 - Inspections have increased in scrutiny, and this will ramp up further over time.
 - Consequences: 483; Warning Letter; Injunction



Science-Based Groupings

Jim Dickson

Iowa State University





Purpose

- “It is FDA’s policy that challenge studies on one product may sometimes be applicable to other products”
- **“scientific and technical justification** for selecting a **subset of spices for validation**, with the understanding that once the subset is validated, the results are applicable to the entire predefined group of spices”



Surrogates

- **Surrogates are necessary to validate process in the processing environment**
- **A surrogate should respond to the intervention in a manner similar to the pathogen in question**
- **The results of the intervention on the surrogate must be able to be correlated with the expected results of the pathogen**
- ***E. faecium* has been demonstrated to be adequate for validation with steam, gas and irradiation**



Process Characteristics

- **Steam:**
 - **density**
 - **water activity**
 - **steam temperature and pressure**
 - **exposure time**
 - **Vacuum**
 - **come-up time or prewarming**
 - **flow rate**
 - **packaging**



Process Characteristics

- **Gas:**
 - **Density**
 - **gas concentration**
 - **gas pressure**
 - **relative humidity**
 - **Temperature**
 - **exposure time**
 - **packaging**



Process Characteristics

- **Irradiation:**
 - **Density**
 - **minimum absorbed dose**



Intrinsic Characteristics of Spices

- **Part of the plant:**
 - may be an initial factor to consider
 - herbs have more surface area and lower density compared to berries
 - A validation process developed for cilantro would be more likely to translate to other herbs compared to black pepper



Intrinsic Characteristics of Spices

- **Product form:**
 - the form of a spice or herb is often changed through cutting or milling
 - Ground product will have higher surface area and higher density compared to its whole
 - there may be different considerations for validation of a ground product than for its whole form



Intrinsic Characteristics of Spices

- **Water activity:**
 - **Thermal Processes - As water activity decreases, thermal resistance increases**
 - **Fumigation processes - reduced relative humidity reduces the efficacy of the treatment**
 - **Irradiation – impact of water activity less clear**

Intrinsic Characteristics of Spices

Water Activity (a_w) Range	Spices
0.3 to 0.4	Garlic, onion, cumin, coriander, oregano powder and parsley leaves
0.4 to 0.5	Basil leaves, basil powder, rosemary powder, chili powder, mustard, paprika, curry powder, allspice and oregano powder
0.5 to 0.6	Black pepper, cinnamon, nutmeg, cayenne, oregano leaves, mace, turmeric and ginger
0.6 to 0.65	Cloves



Intrinsic Characteristics of Spices

Density:

impacted by the material composition, the particle size, and the water activity.

Irradiation - as density increases, the variation within the process increases.

Intrinsic Characteristics of Spices



Spice	Bulk Density (g/cm ³)	Particle Density (g/cm ³)
White Pepper	0.539	1.01
Black Pepper	0.487	1.27
Red Pepper	0.423	1.07
Paprika Powder	0.438	1.21
Curry Powder	0.401	1.15



Intrinsic Characteristics of Spices

Interactions:

- Water activity and density may interact
- A spice with a higher water activity may also have a higher density
- Higher water activity may make the microorganisms more sensitive to a process, but the higher density may affect the actual performance of the process.



Intrinsic Characteristics of Spices

- Inhibition:**
- Some spices have inherent properties with inhibitory effects on microorganisms**
- These properties could impact a variety of aspects of validation of treatment methods**
 - potential impact on surrogate organism selection**
 - inoculation practices**
 - selection of a representative product for a grouping of spices.**



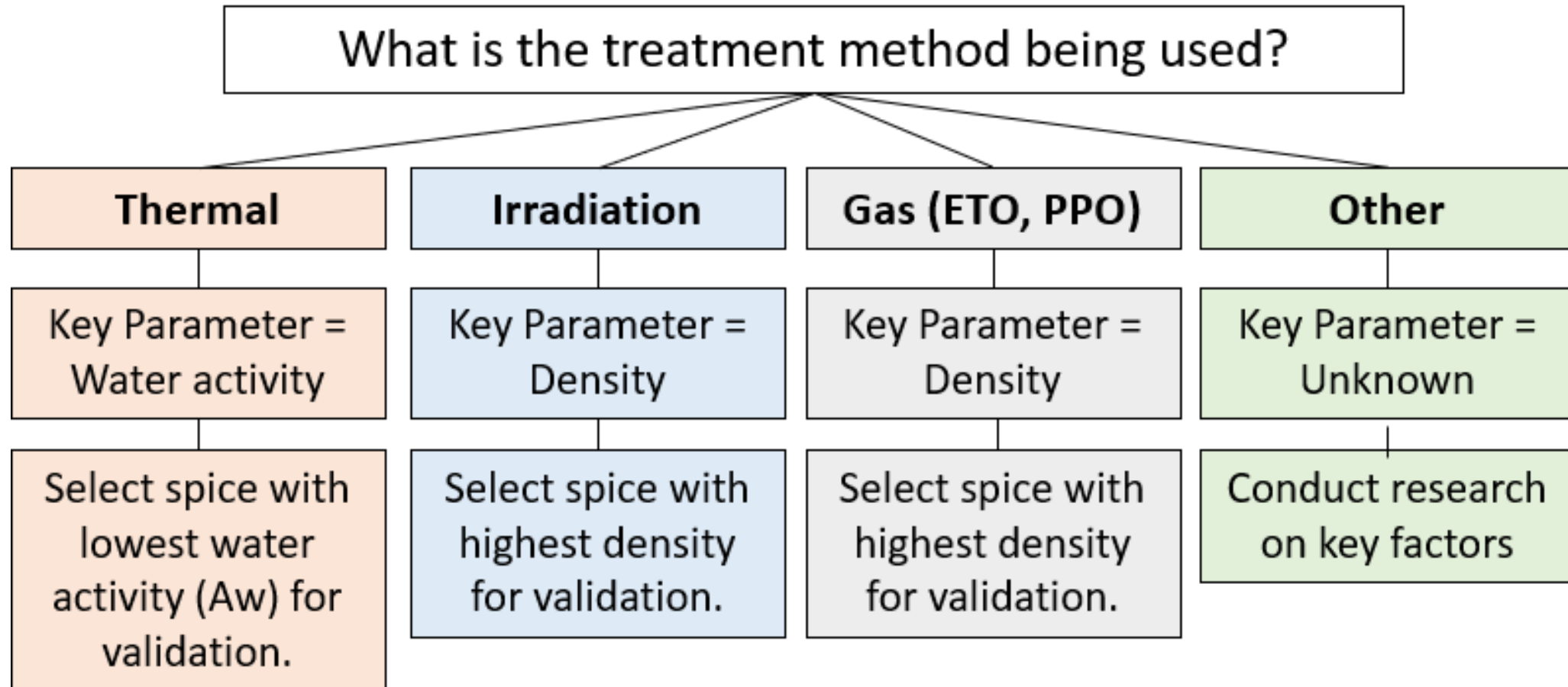
Intrinsic Characteristics of Spices

- Inhibition – Other Considerations:**
- Any process in the validation that increases the moisture content, even temporarily, may enhance the inhibitory properties of the spice**
 - “wet” inoculation**
 - “wet” processing**

Intrinsic Characteristics - Summary

Factor	Impact
Water Activity	As water activity increases, Salmonella resistance decreases in thermal treatment methods.
Density	As density increases, Salmonella resistance increases.
Product Form	The form of the product (ground or whole) may impact the physical parameters. A finer grind will increase Salmonella resistance.
Inhibition	Antimicrobial compounds in low-moisture spices can be activated and enhanced with added water (wet inoculation; steam treatment). For those treatments, using a spice with minimal antimicrobial properties may be recommended. Experimental studies have shown that irradiation and gas treatments are not impacted by microbial inhibition.

Intrinsic Characteristics - Summary



Validate for worst case scenarios



- **Minimum values expected within batch (product and process)**
- **Minimum values expected between batches (product and process)**
- **Interactions between factors**
- **Load configuration and equipment capacity**
- **Accuracy of process control indicators**



Validation Study Design

- **Challenge tests to study inactivation potential and kinetic parameters - ISO 20976-2 (draft)**
- **Basic Experimental Design**
- **Consider various sources of variability linked to:**
 - **process characteristics**
 - **formulation and product characteristics**

Challenge tests to study inactivation potential and kinetic parameters ISO 20976-2 (draft)



- **Consider:**
 - **Strains of bacteria and preparation**
 - **Inoculation methods**
 - **Number of batches**
 - **Number of sampling points**
 - **Number of samples**
 - **Number of controls**
 - **Report preparation**



Novolyze



Impact of product properties examples

Laure Pujol & Vidya Ananth
Novolyze





The Expert Voice of the U.S. Spice Industry in the Global Market

Agenda

Why water activity has an impact?

Impact of aw

Thermal treatment

ETO treatment

X-ray/irradiation

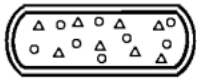
Other impact



Why water activity has an impact?

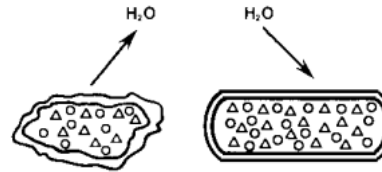


High aw (>0.95)



- Normal state
- Water available

Reduced aw (0.95-0.85)



- No adaptation to the environment
- Bacteria cell very sensitive
- Mechanism to equilibrate water content

Low aw (<0.85)



- Adaptation to the environment
- Production of solute to avoid loss of water
- Modification of the state of the cell
- Implies more resistance of the cell

Influence of Water Activity on Foodborne Bacteria — A Review¹

WILLIAM H. SPERBER

Mechanisms of survival, responses, and sources of *Salmonella* in low-moisture environments

Sarah Finn¹, Orla Condell¹, Peter McClure², Alejandro Amézquita² and Séamus Fanning^{1*}



Impact of a_w

Thermal treatment

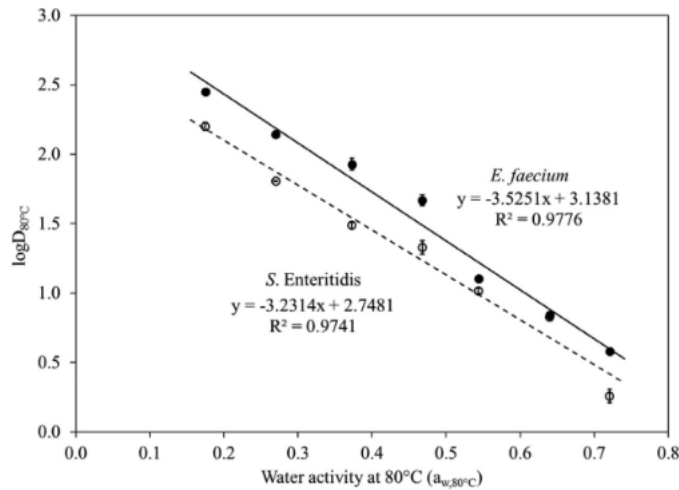
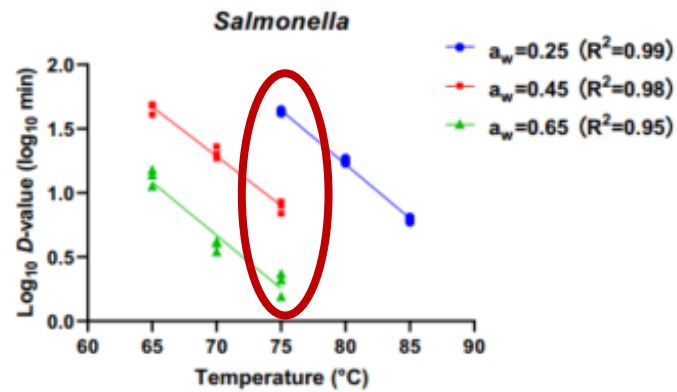


FIG 5 $\text{Log}D_{80^\circ\text{C}}$ (decimal reduction time to achieve 90% population reduction at 80°C) values for *S. Enteritidis* and *E. faecium* in SiO_2 increased with decreasing water activity levels at 80°C ($R^2 = 0.98$).

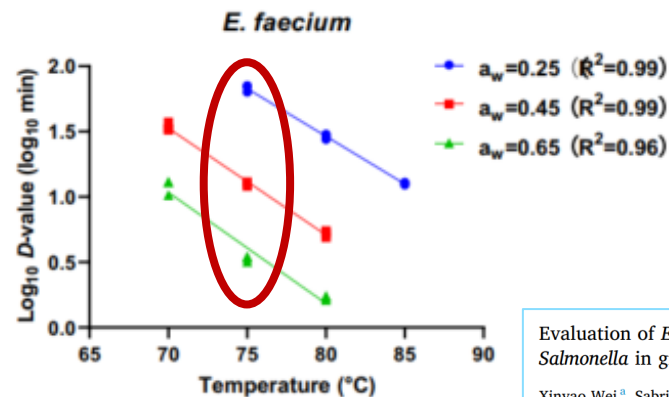
- Thermal resistance at 80°C
- *Salmonella* Enteritidis
- *E. faecium*
- Flour

Exponentially Increased Thermal Resistance of *Salmonella* spp. and *Enterococcus faecium* at Reduced Water Activity

Shuxiang Liu,^a Juming Tang,^a Ravi Kiran Tadapaneni,^a Ren Yang,^a Mei-Jun Zhu^b



- Several temperature
- *Salmonella* cocktail
- *E. faecium*
- Ground black pepper



Evaluation of *Enterococcus faecium* NRRL B-2354 as a surrogate for *Salmonella* in ground black pepper at different water activities

Xinyao Wei^a, Sabrina Vasquez^a, Harshavardhan Thippareddi^b, Jeyamkondan Subbiah^{a,c,*}

Fig. 3. Thermal resistance constants (z -values) of *Salmonella* and *E. faecium* in ground black pepper at different water activities.

Decrease of water activity



Increase thermal resistance



Impact of aw/Relative humidity ETO treatment

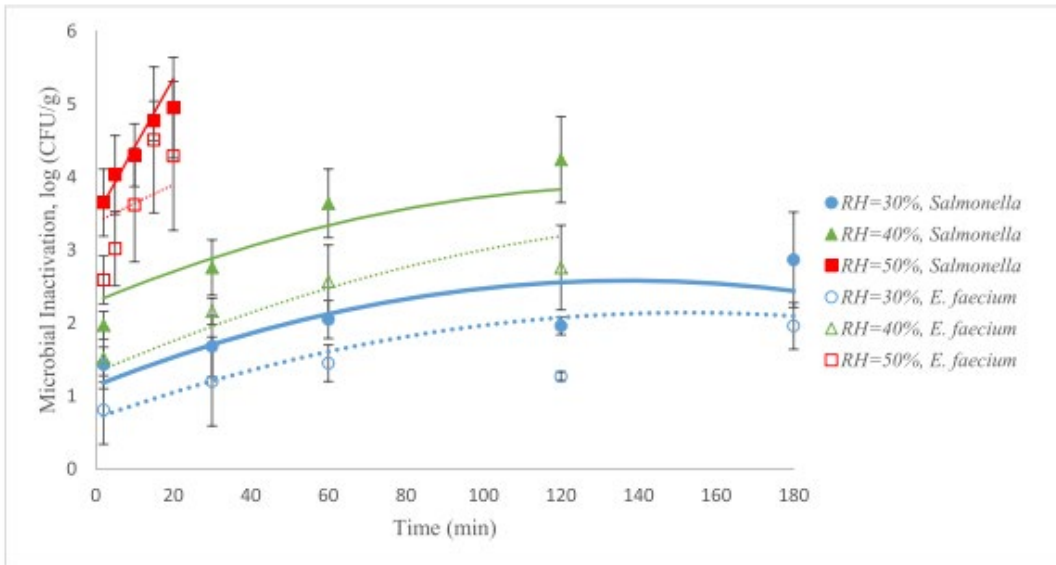


Fig. 1. Inactivation of *Salmonella* and *E. faecium* on cumin seeds during EtO treatment at 30%, 40% and 50% relative humidity (RH) and 46, 53, and 60 °C. Error bars indicate one standard deviation of 3 replications. Trend lines are response surface model predictions.

- ETO+Thermal resistance at 46°C
- *Salmonella* Cocktail
- *E. faecium*
- Cumin seeds

Decrease of water activity
↓
Increase ETO resistance

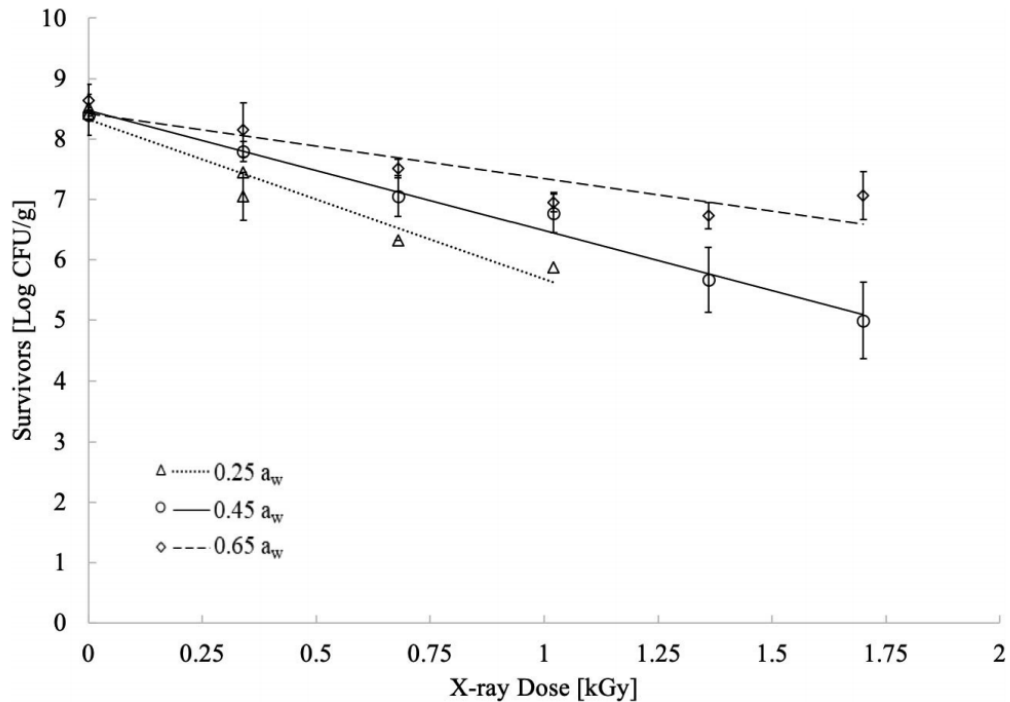
Inactivation of *Salmonella enterica* and *Enterococcus faecium* NRRL B2354 on cumin seeds using gaseous ethylene oxide

Long Chen^a, Xinyao Wei^b, Byron D. Chaves^b, David Jones^a, Monica A. Ponder^c, Jeyamkondan Subbiah^{a,b,d,*}



Impact of a_w

X-ray-irradiation



- X-ray resistance
- *Salmonella* Enteritidis Pt30
- Almond kernel



Decrease of water activity



Decrease X-ray resistance

Effect of Food Structure, Water Activity, and Long-Term Storage on X-Ray Irradiation for Inactivating *Salmonella* Enteritidis PT30 in Low-Moisture Foods

PHILIP J. STEINBRUNNER,¹ PICHAMON LIMCHAROENCHAT,¹ QUINCY J. SUEHR,¹ ELLIOT T. RYSER,² BRADLEY P. MARKS,^{1,2} AND SANGHYUP JEONG^{1*}



Other impact

X-ray-Irradiation

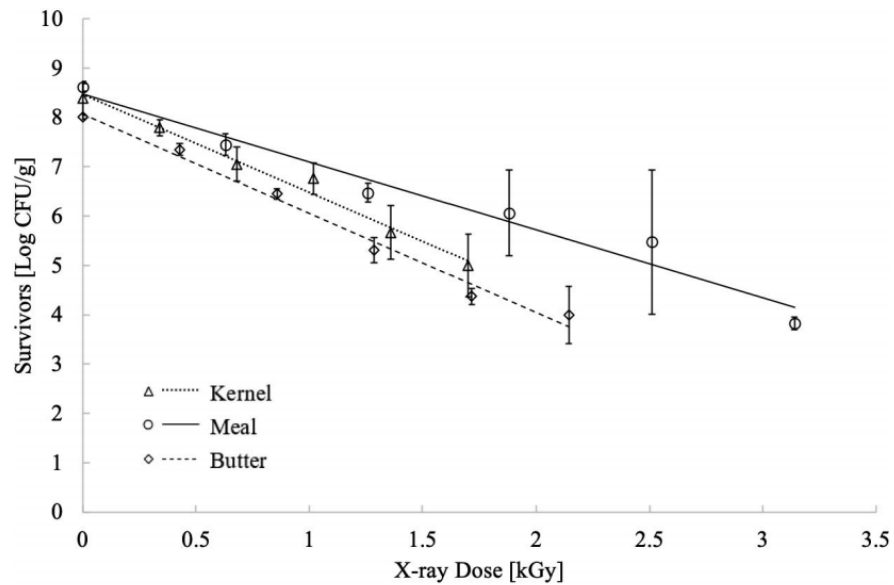


FIGURE 2. Survival (log CFU per gram) of *Salmonella Enteritidis* PT30 (mean values \pm 95% confidence intervals) on X-ray-irradiated almond kernels, meal, and butter at 0.45 a_w .

- X-ray resistance
- *Salmonella* Enteritidis Pt30
- Several forms of almonds

Grinding Almond
kernel



Increase X-ray
resistance

Effect of Food Structure, Water Activity, and Long-Term Storage on X-Ray Irradiation for Inactivating *Salmonella* Enteritidis PT30 in Low-Moisture Foods

PHILIP J. STEINBRUNNER,¹ PICHAMON LIMCHAROENCHAT,¹ QUINCY J. SUEHR,¹ ELLIOT T. RYSER,² BRADLEY P. MARKS,^{1,2} AND SANGHYUP JEONG^{1*}



Other impact

X-ray-Irradiation



TABLE 3. X-ray radiation D_{10} -values from the *Salmonella* Enteritidis PT30 survivor curves for almond, wheat, and date products at 0.25, 0.45, and 0.65 a_w ^a

Product	Type	a_w	D_{10} (kGy)
Almond	Kernel	0.25	0.378 ± 0.120 A ^b
		0.45	0.507 ± 0.078 B
		0.65	0.934 ± 0.285 CD
	Meal	0.45	0.725 ± 0.127 CD
		0.65	0.811 ± 0.075 CD
		Butter	0.45
Wheat	Kernel	0.25	0.774 ± 0.132 CD
		0.45	0.800 ± 0.082 CD
		0.65	0.915 ± 0.073 CD
Date	Flour	0.45	0.607 ± 0.048 BC
	Slice	0.45	2.34 ± 0.406 E
	Paste	0.65	2.01 ± 0.331 E
		0.45	0.922 ± 0.085 CD

^a Values are means ± 95% confidence intervals. Means with the same letter are not significantly different ($\alpha = 0.05$).

^b Only two replicates due to missed dilutions.



Not a systematic relationship

Grinding Wheat kernel



Decrease X-ray resistance

Effect of Food Structure, Water Activity, and Long-Term Storage on X-Ray Irradiation for Inactivating *Salmonella* Enteritidis PT30 in Low-Moisture Foods

PHILIP J. STEINBRUNNER,¹ PICHAMON LIMCHAROENCHAT,¹ QUINCY J. SUEHR,¹ ELLIOT T. RYSER,² BRADLEY P. MARKS,^{1,2} AND SANGHYUP JEONG^{1*}



Example 1* - 4 products / Thermal treatment



Mustard



Mint



Coriander



Basil

- **Step 1:** Classify by the part of the plant



Group 1



Group 2

- **Step 2:** determination of the worst case based on the critical parameter

→ Lowest Aw

Mustard:
0.4-0.5

Coriander:
0.3-0.4

Mint:
0.2-0.4

Basil:
0.5

**Coriander and Mint
to validate**

* From ASTA Guidelines



Example 2* – Leaf products (11 products)

Product	Aw	Density (g/L)
Bay leaves	0.46-0.52	121,7
Dill weed	0.10 – 0.20	209,7
Marjoram	0,32	115
Oregano	0,55	202,9
Parsley	0,32	108,2
Rosemary	0,5	223,2
Sage	0.23-0.29	135,3
Spearmint	0.23-0.38	108,2
Sweet basil leaf	0,5	142
Tarragon	0.33-0.36	121,7
Thyme	0,5	182,6

- **Step 1:** Classify by the part of the plant → only leaf product

- **Step 2:** Determination of the worst case based on the critical parameter

Known critical parameter

Thermal treatment

Critical parameters: aw

Dill weed to validate

Irradiation

Critical parameters: density

Rosemary to validate

Unknown critical parameter

Several options

- Validation of the 2 products
- Group can be split into subgroups
- Modify the worst case, for example grinding the product
- Other factors to consider ?

* From ASTA Guidelines



The Expert Voice of the U.S. Spice Industry in the Global Market

Take home message

- Factors to consider is depending on the type of technology applied
 - Thermal, Gas, Irradiation
 - Others
- Intrinsic properties to consider
 - Water activity
 - Particle size/form, density
 - Antimicrobial properties
 - Fat and other intrinsic properties of the product





Questions!

