Validation of Antimicrobial Processes for Spices

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Food and Drug Administration

- Validation: 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. (21 CFR 117.3)

- FSMA guidance document on validation coming “soon”

Available Research - Surrogates

- Validation of *Enterococcus (Pediococcus) faecium* as a surrogate
  - Steam/Heat
  - Gas
  - Irradiation
- Other surrogates may be used if they can be supported with data

Validation of *Enterococcus faecium* as a surrogate – Steam and Irradiation

- **ILSI and ASTA sponsored research**
  - **Inactivation of *Salmonella enterica* and Surrogate *Enterococcus faecium* on Whole Black Peppercorns and Cumin Seeds Using Vacuum Steam Pasteurization. Frontiers Sustainable Food Sys. 2 (2018):48**
  - **Identification of a Surrogate to Validate Irradiation Processing 1 of Selected Spices. LWT Food Sci. Technol. 102 (2019) 136–141.**

Validation of *Enterococcus faecium* as a surrogate – Steam and Irradiation

- Research demonstrated that *E. faecium* is an acceptable surrogate
  - Validation studies are influenced by the method of inoculation
- There is no "perfect" surrogate that will predict *Salmonella* results under every possible condition
- Research was presented to FDA and generally well received

Validation of *Enterococcus faecium* as a surrogate - Ethylene Oxide

- Ethylene Oxide Fumigation for Inactivation of *Salmonella* spp. in Black Peppercorn. Xinyao Wei, Long Chen , Soon Kiat Lau, Harshavardhan Thippareddi, Jeyamkondan Subbiah (IAFP poster 2019)
- Inactivation of Inactivation of *Salmonella enterica* and *Enterococcus faecium* in Cumin Seeds Using Gaseous Ethylene Oxide in Cumin Seeds. Long Chen, Xinyao Wei, Soon Kiat Lau, Jeyamkondan Subbiah (IAFP poster 2019)

Validation of *Enterococcus faecium* as a surrogate - Ethylene Oxide

- Research will be published in peer-reviewed journal
- Researchers made a summary available to the Validation Committee

- *"E. faecium* was found to be a suitable surrogate for *Salmonella* during EtO fumigation"

Spice Groupings

- **FDA Concerns:**
  - **FDA has said that they do not believe it is necessary to validate every spice with every process**
  - **Spices are inhibitory: does the spice inhibit the surrogate to a greater degree than *Salmonella*?**

Spice Groupings

- **ASTA has conducted research that shows that *E. faecium* and *Salmonella* are inhibited to the same degree by the most inhibitory spices**

- **ASTA has a summary document which defines spice groupings**

ASTA Guidance Document on Validation

- Team approach to plan
- Develop a plan
- Identify variability
  - Product
  - Process
- Test protocols
- Prepare a report

Other Guidance Documents

INTERNATIONAL STANDARD **ISO 20976-1**

Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products —

Part 1:

Challenge tests to study growth potential, lag time and maximum growth rate

EURL *Lm* TECHNICAL GUIDANCE DOCUMENT

for conducting shelf-life studies on *Listeria monocytogenes* in ready-to-eat foods

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