FDA perspective on approaches for treating spices to increase safety

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Process efficacy…

…is **product** *and* **process** dependent.

Product parameters

- Part of plant
- Product form
- Bulk density
- Particle size
- Water activity (a_w)
- Antimicrobial properties

Process specific considerations

- Process technology
  - Conventional vs Emerging
  - Understand how process may affect and interact with product
- Mode of inactivation (e.g., thermal, chemical, radiation)
- Percent of capacity used (partial vs. full load)
- Bulk packaging during process (if applicable)
  - Size and arrangement of bags/containers
  - Impermeable (polyethylene) vs. porous (burlap)

Black pepper

- Product
- Process
- Process stage
- Particle size
- Bulk density
- Water activity (a_w)
- Antimicrobial properties

Steam

- Time and Temperature conditions
- Cold spot / temperature mapping

Black pepper

- Product
- Process
- Process stage
- Particle size
- Bulk density
- Water activity (a_w)
- Antimicrobial properties

Gas
(ETO, PPO)

- Concentration
- RH
- Exchanges
- Hold time
- Packaging
- Pallet stacking/layout
- others?...

Documentation: Product

- General description of the product(s) or product grouping being validated
- Critical formulation parameter(s) and threshold level(s) (e.g. moisture content, a_w)
  - Consideration given for variability in formulation (i.e. batch-to-batch variability)
- Products covered by the parameters that were validated
- Products not validated or not achieving an adequate log reduction

Documentation: Process Equipment

- General description of the production line: flow chart, schematics, pictures
- Detailed description of process equipment being validated
  - Manufacturer and model number, and perhaps serial number
  - Detailed description of operating principles (operators manual is often not enough)
  - Monitoring and controlling devices (*e.g.* temperature, flow rate)
- Tests supporting validation/product grouping (e.g., temperature distribution)

FDA Observations

- Description of processing system not given
- Critical factors for process control not clearly identified
- Test conditions are not always described
- Process variability is not always considered

Minimal data provided

Does this process **consistently produce a <u>minimum</u>** log count reduction?

- Only the **average** reduction reported
- Just a few samples were tested
- Many studies with only a single replicate

Applying results of one study to another similar food

- Challenge studies on one product may sometimes be applicable to other products.
- The more similar the composition the more likely the study will apply.
- May not be applicable when significant differences in intrinsic properties between products exist.
  - Process stage
  - Particle size

Grouping and similar product considerations

- Part of plant
- Product form
- Water activity (a_w)
- Bulk density
- Inhibitory compounds
- Particle size
- Product composition
- Thermal properties
- Lot-to-lot/seasonal variability

Tests to support product grouping

- Dose/temperature mapping studies
- Heat penetration studies
- Product residence time studies

Example performance standards

- 5 log reduction for fruit and vegetable juices
- 5 log reduction for in-shell egg pasteurization
- 4 log reduction for pasteurized almonds
- 6 log reduction for pasteurized milk
- 8.75 log reduction for pasteurized liquid egg
- 12 log reduction for sterilization of LACF

Summary and process recommendations

- The validation report should summarize the scientific criteria that justify that the specific process consistently provides an acceptable level of process lethality.
- Identify a list of critical parameter(s), critical threshold level(s) and operating limit(s)
- Provide procedures for managing process deviations

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