Validation: Pathogen-Reduction Steps

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1. Scroll down to “Product Safety"
2. Select View/Download:
   “Validating the Reduction of Salmonella and Other Pathogens in Heat Processed Low-Moisture Foods”
3. Create a password
4. Download document

Webinars also available
Some materials from the webinars are used here.
Conducting a Validation

1. Assess and improve current systems
2. Assemble the Validation Team
3* Determine the most resistant pathogen
   Conduct a hazard analysis
   Consider the level of inactivation needed
   Identify preventive control(s) for hazards reasonably likely to occur
   Assess the impact of the food matrix
4* Validate the efficacy of the lethal process
   Define specific equipment and operating parameters
   Prevent recontamination

Adapted from: AIOE, 2012

Is the process ready to be validated?

- Described
  - Operational procedures are in place and operational limits are stated.
  - Analytical procedures exist.

- Measurable
  - Process
    - measures are accurate and precise.
    - records are in place.
  - Calibrated equipment is used.

- Controlled
  - The process meets required operational limits (temperature, retention time, formulation, $a_w$, moisture, etc.)
  - Correction occurs when out of control

- Reproducible
  - Process outputs are within spec day-to-day, season-to-season

Adapted from: AIOE, 2012
Assemble the Validation Team

Include persons familiar with…

- The process
- Product formulation
- Validation data collection
- HACCP requirements
- Experimental design
- Process documentation
- Recordkeeping, record review
- Sample handling
- Data interpretation
- Reporting results

Such as…

- Equipment operators
- Quality management
- Statistician
- Microbiologist
- Engineer
- Product developer

Credit: AIOE, 2012

Identifying Most Significant Pathogens of Public Health Concern

- Reasonably likely to occur
  - Epidemiology
    - Outbreaks, recalls, surveys
  - Ecology
    - Production/processing
    - Product (intrinsic factors)
  - Product
    - How is it handled
    - How is it prepared and consumed
    - What is the shelf life

Credit: CDC
### Potential Preventive Controls

<table>
<thead>
<tr>
<th>Food/Ingredient</th>
<th>Process</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coconuts</td>
<td>Baking</td>
<td>Dehydrators</td>
</tr>
<tr>
<td>Dried fruit</td>
<td>Blanching</td>
<td>• Continuous</td>
</tr>
<tr>
<td>Fruit leathers</td>
<td>Dehydration</td>
<td>• Batch</td>
</tr>
<tr>
<td>Peanuts</td>
<td>Drying</td>
<td>Preconditioners</td>
</tr>
<tr>
<td>Peanut butter</td>
<td>Dry Roasting</td>
<td>Propylene Oxide Chamber</td>
</tr>
<tr>
<td>Tree nuts</td>
<td>Infrared</td>
<td>Roasters (often continuous)</td>
</tr>
<tr>
<td>Nut butters</td>
<td>Oil Roasting</td>
<td>• Rotary</td>
</tr>
<tr>
<td>Nut Products</td>
<td>Radio Frequency</td>
<td>• Flatbed</td>
</tr>
<tr>
<td></td>
<td>Steaming</td>
<td>• Oil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Steam tunnels</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vacuum/heat</td>
</tr>
</tbody>
</table>

Adapted from: AIOE, 2012

### Most resistant pathogen

- Microorganisms of public health concern
  - reasonably likely to occur

- Process(es)
  - Pathogen(s) most resistant to process
    - May differ by process

- For low moisture foods AT THIS TIME
  - *Salmonella* is generally accepted as the most resistant pathogen (desiccation tolerance, history, epidemiology)
    - Research underway to “validate” this assumption
Salmonella more resistant than E. coli O157:H7 on almonds during desiccation and heating in oil at 121°C/250°F for 1 min or dry heating (laboratory) at 135°C/275°F for 40 min.

Reduction log CFU/g

3 Days desiccation | Hot Oil | Dry Oven
---|---|---
Red | Salmonella Enteritidis PT30
Yellow | E. coli O157:H7 1996 apple cider outbreak
Green | E. coli O157:H7 2006 spinach outbreak

Consider level of inactivation needed

- Regulations
  - 7 CFR 981.442(b) USDA, 2007
  - Minimum 4 log reduction of Salmonella in almonds
  - FDA letter to industry
    - Peanut products (FDA, 2009); Pistachio products (FDA, 2009)
      - Adequately reduce Salmonella (e.g., 5 log)
- Publications
  - Schaffner et al., 2013. Issues to consider when setting intervention targets with limited data for low-moisture food commodities: A peanut case study
    - A 5-log reduction in the absence of any data to establish a target log reduction is science-based and appropriate
- Even if there is a regulatory requirement, a risk assessment may be appropriate to determine if the regulatory requirement is appropriate.
Impact of Food Matrix

- Level of microbial reduction significantly impacted by:
  - Product properties (intrinsic properties)
    - $A_w$
    - composition (fat, protein, carbohydrates)
    - Size, shape
  - Surface properties
    - Skin, shell

Higher moisture levels increase reduction of Salmonella

New ABC guidelines for validation ≤6% moisture
Water activity may be measured instead of moisture
Nut type can influence reductions of *Salmonella*

Log reduction of *S. Enteritidis* PT30 on inoculated nuts heated in hot oil at 250°F for 1 min (n = 3)

![Bar chart showing log reduction CFU/g for Almonds, In shell pistachios, and Hazelnuts.](image)

### Validation Options

1. **Use scientifically valid data**
   Peer reviewed scientific articles or validation guidelines. Treatment simulated in a lab and conditions confirmed in plant.

2. **Conduct experiments**
   Laboratory studies, pilot plant, equipment, processing facility.

3. **Use mathematical modeling**
   Use mathematical modeling with Thermal Death Time data.

4. **Combination of approaches**

*Codex (2008) and Scott (2005)*
Written Validation Plan

- Background
- Team members, roles and responsibilities
- Objectives of the study
- General description of tests; the approach to be taken
- Test site
- Proposed test schedule
- Required approvals
- Products to be validated
- Processes to be validated
  - Schematic, flow chart, equipment settings during testing

Written Validation Plan

- Physical tests
  - Temperature mapping or heat transfer distribution studies
  - Heat penetration studies
  - Product residence time studies
  - Moisture/Aw studies
  - Relative humidity mapping
- Other physical or analytical tests to be performed
- Required equipment for tests
- Microbiological tests
- Mathematical modeling approach and tests
Using Existing Scientifically-Valid Data

- Peer reviewed scientific articles
  - Need translation to commercial application
- Published processing guidelines (current)
  - E.g., Almond Board Guidelines*
- Equipment manufacturer data
- In-facility data

Blanched Almonds ABC (2007)

Hazard Analysis
Salmonella spp., 4-or-5-log reduction

Validation Pathway
Simulated the process in a lab
ABC Supporting Document DOC002
Harris et al., 2012

Confirm in-plant process conditions

- **Time:** In hot water
- **Temperature:** At the coldest point of the immersion
- **Lethality:** Time and temperature combinations demonstrate log reduction

5-log reduction:
- 3.09 min @ 180°F
- 2.00 minutes @ 190°F

Credit: AIOE, 2012
If you aren’t an almond…..

- Data from existing validation study must be “substantially similar” to the food and manufacturing process.
  - Additional laboratory experiments may be needed
  - Pilot-scale studies
    - May be an option
  - Expert assistance to interpret existing published studies or available unpublished data

Conducting Experiments

- In-Process Measures
  - $A_w$, relative humidity, or other in-process measures
- Temperature distribution
  - Temperature mapping
  - Heat penetration
  - Resident times

- “Best”, “Average”
  - Not as important as ranges and boundaries
  - “Worst case”
Temperature mapping

- Identify worst-case, lowest temperature process conditions.
- Wired or wireless probes may be used.
  - A number of options are available

Temperature mapping

- Results are used to confirm minimum temperatures and for process correction.
Residence time

- Direct observation (ovens, screw blanchers, etc.)
  - Belt speed, dial settings, Hz settings, RPM
- More challenging equipment
  - Ovens with tumble

Credit: AIOE, 2012

In facility microbiological studies

- Determine that process is ready for microbial challenge study
- Microbiological challenge studies
  - Appropriate surrogates
    - Count-reduction studies
    - End-point studies
- Studies should be replicated
  - More than one time over more than one lot to demonstrate consistency of results

Credit: AIOE, 2012
In facility tests

- Pass inoculated product through lethal process
  - mimic real production volumes and conditions
- Recover inoculated samples
  - Segregated by color or physical barrier
- As appropriate
  - collect samples from various points in the lethal process (i.e. locations or depths in a bed) to assure full understanding of process variability
- Chill all samples between recovery and analysis
- Enumerate inoculated organisms
  - enrich samples as appropriate/possible
- Report results as log reductions
  - Generate summary tables, averages, min, max
  - Maintain organized raw data

Physical barriers (for holding inoculated product)

- Should be appropriate to the task
- Allow air flow, if necessary
- Not contribute to reduction
  - Create pocket of higher or lower temperatures
Mathematical Modeling

- No publicly accessible low-moisture models currently exist.
- Studies are underway in some commodities
  - GMA (2011): peanut paste and oil
- Processors may conduct their own studies
  - TDT data and process data (retention time, temperature, product $a_w$/moisture)
- Use an expert microbiologist and statistician

Translation to process control

- Critical control points
  - Based on validation documentation
- Operational limits vs critical limits
- Process limits
  - E.g., time, temperature, pressure, relative humidity
- Product limits
  - E.g., water activity, moisture, pH, antimicrobials
Monitoring and Record Review

- Monitoring Program
  - Schedule monitoring based on risk mitigation strategy
  - Define expectations in monitoring and in documentation of results
    - Define actions to be taken when things go wrong
  - Use calibrated continuous monitoring devices where possible – minimize the human factor
  - Design checks & balances that verify successful execution of the monitoring activities – audit all aspects
- Record Review
  - Schedule regular review process & frequencies
  - Employ a contingency plan for the review process
  - Have a strategy for when records don’t meet expectations

Validation Documentation

- Documentation Important
  - Internally
  - Externally
    - Routine
      - Audits, Inspections
    - Crisis
      - Recalls, Outbreaks
- Critical that documentation is:
  - Well organized
  - Clearly presented
  - Developed for external reviewer

Credit: AIOE, 2012
Validation Documentation

- Company information
- Contact information for the author(s)
- Production line(s) validated
- Product description
- Validation methodology
  - Reference to relevant literature
  - Justification for choices made
  - Microbiological tests
  - Modeling
- Results summary
- Critical control parameters and how they are controlled, and monitored, record keeping and review
- Handling procedures for products produced during deviations in processing
- Conclusions and recommendations
  - Limitations of validation
  - Raw data appendix

Supporting roles

- Programs needed to ensure validated process remains valid:
  - Calibration program
  - Preventative maintenance program
  - Management of change control program
  - Comprehensive training program

Credit: AIOE, 2012
Summary

- Validation of processes part of HACCP
  - Important to determining critical limits of processes
- Validation will be an important part of the Preventive Controls Rule
  - Expectations on scientific rigor of validation documentation will increase
- Monitoring and verification in the plant show compliance to validated limits.
- Food Safety Plan also includes
  - Protecting the product after processing