Low-moisture foods validation:
An overview of methods

Presentation to the
GMA Science Forum      April 4, 2012

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Discussion points

A. Introduction
B. Six essential steps for pasteurization
C. Further information
D. Final thoughts
E. References
A portfolio of well recognized, leading brands
Low Moist. Food *Salmonella* presence

*Salmonella* has been associated with low moisture foods

- Beef jerky – 2011
- Milk Powder – 1973
- Infant cereal – 1995
- Toasted oat cereals – 1998
- Tahini, Halva – 2002
- Almonds – 2003, 2004
- Pistachios – 2009

... and low moisture ingredients

- Fish meal – 1972
- Hydrolyzed Vegetable Protein - 2010
- Milk Products – 2009
- Peanut Butter – 2008, 2009
- Chocolate – 1970 - 2006
- Children’s snacks – 2007
- RTE Cereal – 2008
- Pet food Pet foods – 2006 +
- Pet teats: 2003 +
### Many foods and processes

<table>
<thead>
<tr>
<th>Food / Ingredient</th>
<th>Process</th>
<th>Thermal Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chocolate, choc. liquor, cocoa powder</td>
<td>Baking</td>
<td>Baking ovens – continuous belt, continuous carts, batch</td>
</tr>
<tr>
<td>Coconuts</td>
<td>Blanching</td>
<td>Cooking kettles</td>
</tr>
<tr>
<td>Confections</td>
<td>Drying</td>
<td>Drying ovens – batch, continuous</td>
</tr>
<tr>
<td>Dried fruit, fruit leather</td>
<td>Dry Roasting</td>
<td>Expanding/puffing equipment</td>
</tr>
<tr>
<td>Dried Jerky, Milk, Egg</td>
<td>Expansion/Puffing</td>
<td>Pre-Conditioners, Extruders</td>
</tr>
<tr>
<td>Dried vegetables</td>
<td>Extrusion</td>
<td>Screw steaming</td>
</tr>
<tr>
<td>Gelatin</td>
<td>Frying</td>
<td>Steam vessels</td>
</tr>
<tr>
<td>Grains and flour</td>
<td>Infrared</td>
<td></td>
</tr>
<tr>
<td>Gums/thickeners (excluding xanthan)</td>
<td>Microwave</td>
<td></td>
</tr>
<tr>
<td>Tree nuts (e.g., almonds, pistachios)</td>
<td>Oil Roasting</td>
<td></td>
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<tr>
<td>Nut products</td>
<td>Radio Frequency</td>
<td></td>
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<tr>
<td>Peanuts, Peanut Butter</td>
<td>Steaming</td>
<td></td>
</tr>
<tr>
<td>Pet Treats</td>
<td></td>
<td></td>
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<tr>
<td>Ready-to-Eat Cereals</td>
<td></td>
<td></td>
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<tr>
<td>Seed kernels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tahini</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B. Six essential steps for pasteurization from NACMCF (2006)

Journal Food Protection 69:1190-1216
B. Essential steps for Pasteurization

1. Identify **microorganisms** of public health concern.
2. Determine the **most resistant pathogen**.
3. Consider the **level of inactivation** needed.
4. Assess the **impact of the food formulation** on pathogen survival.
5. Validate the process applied.
6. Determine **critical limits** & **equipment operating parameters**.

Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization

NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

### B. Steps: Moist food examples

<table>
<thead>
<tr>
<th>Step</th>
<th>Low-Acid examples</th>
<th>Acid/Acidified examples</th>
</tr>
</thead>
</table>
| 1. Microorganisms of concern | • *C. botulinum*  
  • *C. perfringens*  
  • *S. Aureus* | • *Salmonella*  
  • *E. coli O157:H7*  
  • *Bacillus spp.* (e.g., *B. licheniformus*) |
| 2. Most resistant pathogen | • Heat resistance determined by Thermal Death Time (TDT)  
  • (Or resistance to H$_2$O$_2$ or preservatives, or example) |  |
| 3. Level of inactivation needed | • e.g., 12D process for *C. botulinum* | • e.g., 5D process for pathogens |
| 4. Impact of food formulation | • High pH, high-moisture | • Low pH, high-moisture |
| 5. Validate the process applied | • Temperature distribution and heat transfer distribution tests  
  • Heat penetration tests  
  • Retention time studies  
  • Modeling (process calculations, flow characteristics)  
  • Microbial count-reduction tests |  |
| 6. Critical limits and operating parameters | Process time, temperature, product Initial Temperature | Formulation (pH) control, Process time, temperature, product Initial Temperature |
### B. Steps: Low-Moisture Foods (LMF)

<table>
<thead>
<tr>
<th>Step</th>
<th>Low-moisture foods examples</th>
</tr>
</thead>
</table>
| 1. Microorganisms of concern | - *Salmonella* spp.  
- *E. coli* O157:H7  
- *Listeria* spp. |
| 2. Most resistant pathogen | - Heat resistance determined by Thermal Death Time (TDT)  
- Resistance to preservatives, inhibitors |
| 3. Level of inactivation needed | - Requirement of regulation or guidance  
- Determined through risk assessment of raw materials |
| 4. Impact of food formulation | - Low moisture increases heat resistance; potential pathogen survival, although no growth  
- pH control and preservatives are sometimes used |
| 5. Validate the process applied | - Temperature distribution and heat transfer distribution tests  
- Heat penetration tests  
- Retention time studies  
- Modeling (process calculations, flow characteristics)  
- Microbial count-reduction tests |
| 6. Critical limits and operating parameters | Formulation (e.g., pH, aw) control, process time, process temperature, product Initial Temperature, relative humidity |
Step 1: Identify microorganisms of public health concern.
Potential pathogens of concern for growth* based on $a_w$ and pH  (NACMCF, 2010)

<table>
<thead>
<tr>
<th>$a_w$</th>
<th>&lt; 3.9</th>
<th>3.9 - &lt;4.2</th>
<th>4.2 – 4.6</th>
<th>&gt;4.6 – 5.0</th>
<th>&gt;5.0 – 5.4</th>
<th>&gt;5.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.88</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
</tr>
<tr>
<td>0.88–0.90</td>
<td>NG</td>
<td>NG</td>
<td>NG</td>
<td>Staphylococcus aureus</td>
<td>S. aureus</td>
<td></td>
</tr>
<tr>
<td>&gt;0.90–0.92</td>
<td>NG</td>
<td>NG</td>
<td>S. aureus</td>
<td>S. aureus</td>
<td>L. monocytogenes</td>
<td>S. aureus</td>
</tr>
<tr>
<td>&gt;0.92–0.94</td>
<td>NG</td>
<td>L. monocytogenes Salmonella</td>
<td>Bacillus cereus Clostridium botulinum L. monocytogenes Salmonella S. aureus</td>
<td>B. cereus C. botulinum L. monocytogenes Salmonella S. aureus</td>
<td>B. cereus C. botulinum L. monocytogenes Salmonella S. aureus</td>
<td></td>
</tr>
<tr>
<td>&gt; 0.94–0.96</td>
<td>NG</td>
<td>L. monocytogenes Pathogenic E. coli Salmonella S. aureus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus Vibrio parahaemolyticus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus Vibrio parahaemolyticus</td>
<td></td>
</tr>
<tr>
<td>&gt; 0.96</td>
<td>NG</td>
<td>Salmonella Pathogenic E. coli Salmonella S. aureus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus Vibrio parahaemolyticus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus Vibrio parahaemolyticus V. vulnificus</td>
<td>B. cereus C. botulinum L. monocytogenes Pathogenic E. coli Salmonella S. aureus Vibrio parahaemolyticus V. vulnificus</td>
<td></td>
</tr>
</tbody>
</table>

*Does not include pathogen survival, or spoilage organisms. (See important notes in the article regarding Campylobacter, Shigella and Yersinia spp.).
Step 2: Determine the most resistant pathogen.

Thermal Death Time methods will be discussed in detail by Carrie Ferstl, Manager, Research Microbiology, The National Food Laboratory.
Heat resistance in Dry Animal Feeds

*S. sentfenberg resistance in Dry Animal Feeds*


D-value (minutes) for 1-log reduction

Temperature (°F)

Percent Moisture

- 5%
- 10%
- 15%
- 20%
- 25%

$z = 19.82 \, F^\circ$

* The processor may determine resistance relative to $a_w$. 
For other resistance (e.g., pH, preservatives, antimicrobials) Consider NACMCF (2010)


Supplement

Parameters for Determining Inoculated Pack/Challenge Study Protocols

ADOPTED 20 MARCH 2009, WASHINGTON, D.C.
NATIONAL ADVISORY COMMITTEE ON MICRO BIOLOGICAL CRITERIA FOR FOODS

NACMCF Executive Secretariat,* U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science, Room 333 Aerospace Center, 1400 Independence Avenue S.W., Washington, D.C. 20250-3700, USA

J. Food Prot. 73:140-202
Step 3:
Consider the level of inactivation needed.
LMF level of inactivation

- Through risk assessment by company/industry.
- Dictated by laws or guidance.

Examples:

<table>
<thead>
<tr>
<th>Reduction</th>
<th>Food</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.5 log</td>
<td>Meat jerky (for humans)</td>
<td>9 CFR 318.17</td>
</tr>
<tr>
<td>7.0 log</td>
<td>Poultry jerky (for humans)</td>
<td>9 CFR 381.150</td>
</tr>
<tr>
<td>4.0 - 5.0 log</td>
<td>Almonds</td>
<td>7 CFR 981.442</td>
</tr>
<tr>
<td>5.0 log*</td>
<td>Peanut products</td>
<td>FDA guidance (2009a)</td>
</tr>
<tr>
<td>5.0 log*</td>
<td>Pistachio products</td>
<td>FDA guidance (2009b)</td>
</tr>
</tbody>
</table>

*presumptive
Step 4: Assess the impact of the food formulation on pathogen survival.
Impact of the Food Matrix

- Increased *Salmonella* resistance occurs with increased solids, lower moisture/\(a_w\).
- Reduced *Salmonella* resistance can come from bacteriocins and other additives (Doyle et. al, 2000).
- If testing the impact of the food matrix, use a qualified microbiology laboratory.

Useful references:

- Thermal Death Time study methods (e.g. NFPA, 1978 or Stumbo, 1973) or published articles for Low-moisture food TDTs.
Step 5: Validate the process applied.

- Definitions
- Validation team
- Methods
<table>
<thead>
<tr>
<th>Codex definition (adapted)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Validation</strong>: Obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome.</td>
<td>Validation is typically performed when a processing step is designed, or for ‘concurrent’ validation. Scientific or technical information is collected in order to provide evidence that the food safety objective can be met.</td>
</tr>
<tr>
<td><strong>Monitoring</strong>: Conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.</td>
<td><strong>Data are taken during production</strong> of the monitored food, and records are kept for later review. Monitoring may include time and temperature readings from process equipment, or product moisture/$a_w$ readings to assure minimum required levels.</td>
</tr>
<tr>
<td><strong>Verification</strong>: Determining whether a control measure is operating as intended.</td>
<td>Verification activities may include <strong>record review</strong> to assure that a process system in control.</td>
</tr>
</tbody>
</table>

(Codex, 2008)
The validation team

- Designs, conducts, evaluates and implements
  Include persons familiar with…

- The process
  - Equipment operators, process engineers, quality assurance,
  - Food technologists, physical chemists, food safety professionals

- Validation **data collection**

- HACCP principles

- Documenting, implementing critical limits

- Accepted micro methods
  - Microbiologist and statistician
Methods to validate processes

**Codex**: *Guideline for the Validation of Food Safety Control Measures* (CAC/GL 69-2008)


1. Use scientifically valid data
2. Conduct experiments
   (microbiological tests, and measures of the system & product)
3. Use mathematical modeling

\[
\sum \left( \frac{(T - T_{ref})}{z} \right)_{\Delta t} / D
\]
Method 1: Use Scientifically Valid Data

- **Sources of valid data:** literature, equipment suppliers, regulatory guidance, previous studies.

- **Justify ‘substantial similarity’ of the product and process to the source data, in the Validation Report,** for example:
  - Retention time in equipment
  - Equipment settings
  - Minimum process temperature
  - Microbial resistance in the food
  - Relative humidity
  - Product Initial Temp.
  - Product moisture/aw

- **Implement formulation and process critical factors from the source document.**
  - Product: Moisture/aw, piece size/shape, etc.
  - Process: Relative humidity, process time & temperature, product initial temperature, bed depth
Examples for Low-Moisture Foods

Meat and poultry jerky
- USDA compliance guidelines (FSIS, 1999) Appendix A
- Published processes, articles at the Center for Meat Process Validation) www.meathaccp.wisc.edu

Almonds
- Almond Board of California (ABC, 2007+) guidelines www.almondborder.com

Dried egg whites
- Industry guidelines (Froning and others 2002) and regulations (9 CFR 590.575) of pasteurization pre-drying

Dried milk from GMA (2009a)
- Industry standard 72°C for 15 sec. pasteurization, pre-drying
Validation

Method 2: Experiments

- **Tests of the system** (Covered by D. Anderson)
  - Temperature mapping; Heat transfer distribution
  - Retention time
  - Other required process conditions (e.g. rel. humidity)

- **Tests of the product** (D. Anderson)
  - Heat penetration studies
  - Analyses (e.g., moisture/aw, preservative level)

- **Microbiological tests** (C. Ferstl)
  - Thermal death time studies
  - Count-reduction tests in lab or in process
  - End-point lethality (presence/absence) tests
Method 3: Modeling

- Few low-moisture mathematical models
- Studies are underway, some commodities
  - GMA (2011): peanut paste and oil - ILSI grant
- Processors may conduct their own studies, using TDT data and process data (retention time, temperature, product a_w/moisture)
- Use an expert microbiologist and statistician for modeling
Step 6:
Determine critical limits and equipment operating parameters.
Create Critical Limits
• Determine critical limits (validation team)

Monitor CCPs during production
• Establish production records
• Create deviation procedures

Verify that the control is working as intended
• Review production records
• Audit the system (monitoring, calibration, GMPs...)
• Consider microbiological monitoring
• Be aware of emerging hazards
C. Further Information
C: Further Information - Validation


• ICMSF Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance (ICMSF, 2011)

• Alliance for Innovation & Operational Excellence (Anderson and Lucore, April 2012)

http://community.pmmi.org/Alliance/Home/
C: Further Information

Guidelines and literature reviews

• Control of Salmonella in Low Moisture Foods (GMA, 2009a)
• Control of Salmonella ... Annex (GMA, 2009b)
• Industry Handbook for Safe Processing of Nuts (GMA, 2010)
• Clean Safe Spices (Amer. Spice Trade Assoc., 2010)
• Salmonella Control Guidelines (American Feed Industry Assoc., 2010)
• Doyle and Mazzotta (2000)
D. Final thoughts…

• Validation activities provide the scientific data to support pathogen control measures.

• Monitoring and verification in the plant can show compliance to validated limits.

• Challenges exist for validating LMF processes
  - D-value increases with lower moisture/aw
  - Little D- and z-value data is found in literature
  - Micro lab challenges: growth, harvest, inoculation
  - Mathematical models are needed
  - Validation methods vary widely


ABC, 2007g. Guidelines for Validation of Propylene Oxide Treatment for In-shell Almonds, v2.0, October 1, 2008. Almond Board of California, Modesto, CA. www.almondboard.com
References


References


FDA (Food and Drug Administration), 2009a. Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product As An Ingredient; Draft Guidance dated June 2009.

FDA (Food and Drug Administration), 2009b. Guidance for industry: measures to address the risk for contamination by *Salmonella* species in food containing a peanut-derived product as an ingredient.


FDA (Food and Drug Administration), 2011b. FY 2012 Nationwide Assignment to Collect and Analyze Samples of Pet Foods, Pet Treats, and Supplements for Pets from Interstate Commerce in the United States for *Salmonella*. Memorandum, October 24, 2011.

References


GMA (Grocery Manufacturers Association), 2009a. Control of Salmonella in Low-Moisture Foods. www.gmaonline.org


References


References


Thank You

Michael Hayes
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