Practical Guidance for Validation Studies: From Start to Finish

Organized by: ILSI Europe

Moderator: Erdogan Ceylan, Merieux Nutrisciencies

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• It is important to note that all opinions and statements are those of the individual making the presentation and not necessarily the opinion or view of IAFP.

• All attendees are muted. Questions should be submitted to the presenters during the presentation via the Questions section at the right of the screen. Questions will be answered at the end of the presentations.

• This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.
Erdogan Ceylan, Ph.D.
Moderator

Organization: Merieux NutriSciences
Function: Fellow, Process Authority, Subject Matter Expert

Work Experience:
- Fellow: 20 years of experience in food safety and quality
- Managed numerous validation studies globally
- IAFP member, Served on JFP Editor Selection Committee
- Vice Chair ILSI working group on Process Validation
- Published numerous peer reviewed articles and book chapters, and given presentations at international meetings
Anett Winkler, Ph.D.

Organization: Cargill Germany
Function: EMEA Microbiologist

Work Experience:
- 20 years at Kraft / Mondelez as microbiologist in various roles (regional / global)
- performed numerous validation studies for nut, dairy & cocoa processing
- global expert for thermal processing within Mondelez International
- joined Cargill in October 2017 in her current role
- also active in ILSI Europe (Microbiology Food Safety), and IAFP being the current chair of the Organizing Committee for the IAFP European Symposium
Roy Betts, Ph.D.

Organization: Campden BRI Group
Function: Research Fellow

Work Experience:

- 36 years at Campden BRI as a Food Microbiologist,
- Food hygiene research - cleaning and disinfection of production
- Major research in the development and validation of test methods
- Practical experience in microbiological risk assessment in food production
- IAFP member, ILSI Microbiological Safety Committee Member
Heidy den Besten, Ph.D.

Organization: Wageningen University
Function: Associate Professor

Work Experience:
- 11 years at Wageningen University as Assistant and Associate Professor
- Editorial board member JFP, IJFM, FRI
- Program committee member IAFP
- ISO working group member
- Chair ILSI working group on Process Validation
Initial Steps
or
How to be prepared for a validation study

Anett Winkler
Validation – What does it mean?

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.
How do you identify your target pathogen(s) / identify hazards?

**Target Pathogen(s) – BE SPECIFIC !!!**

- HACCP Study – hazard analysis (also consider intended use)
- Epidemiological information
- Surveys, published literature (on prevalence, occurrence)

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**Table 5** Levels of *Salmonella* in positive samples of some types of naturally contaminated low water activity foods

<table>
<thead>
<tr>
<th>Product</th>
<th>Where collected</th>
<th>Sample size (g)</th>
<th><em>Salmonella</em> levels (MPN/g)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nut</td>
<td>Almond, raw kernel</td>
<td>100 g × 1 and 3 each: 25 g, 2.5 g, 0.25 g</td>
<td>96 samples: 0.0044 to 0.15; four samples: 0.00080, 0.00080, 0.00095, 0.00034; 10 samples: 0.002 to 0.032</td>
<td>Bansal et al., 2010; Danyluk et al., 2007; Lambertini et al., 2012, Harris, unpubl. (2013 data)</td>
</tr>
<tr>
<td>Brazil nut</td>
<td>Retail, UK</td>
<td>10 g × 10</td>
<td>Two samples: 0.23, 0.09</td>
<td>Little et al., 2010</td>
</tr>
</tbody>
</table>

Source: Ceylan et al, 2021
How do you identify your target pathogen(s) / identify hazards?

- Enterobacteriaceae
- Coliforms
- Salmonella
- Cronobacter
- STEC
- E.coli
- Listeria monocytogenes
- Listeria spp.
Effective Control: How many log reductions are sufficient to control the biological hazard??

Look at

- Prevalence rates and quantitative levels at initial stage
- Exposure assessments
  (including infective / harmful dosage, consumption pattern)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Process</th>
<th>Target organism</th>
<th>Process parameter/criteria</th>
<th>Performance criterion</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat and meat products</td>
<td>Fermented dry sausage containing beef</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>ND</td>
<td>5-log</td>
<td>USDA, 2001</td>
</tr>
<tr>
<td></td>
<td>Cooked beef, roast beef, and cooked corned beef products&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lethality process which must include a cooking step</td>
<td><em>Salmonella</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shorter holding times for temperatures ≥146°F (63.3°C). For example, 86 or 91 s at 146°F (63.3°C) or equivalent. Longer holding times apply for temperatures ≤145°F (62.8°C). For example, 23 to 24 min at 137°F (58.4°C) or equivalent. Inactivation target is considered to be reached instantly at temperatures ≥158°F (30°C).</td>
<td>6.5- or 7.0-log reduction</td>
<td>Code of Federal Regulations, 2009b, Chapter III. Subchapter A. Part 318. Subpart A: Entry into Official Establishments, Retirements and Preparation of Products. Section 318.17; FSIS, 2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat and poultry products</td>
<td>Heating process</td>
<td><em>Salmonella, E. coli</em> O157:H7 for products containing beef</td>
<td>ND</td>
<td>5-log reduction</td>
<td>FSIS, 2014</td>
</tr>
</tbody>
</table>

Source: Ceylan et al, 2021
"Safe Harbors"

- **Low-Acid canned food regulations / guidelines**: “12D Clostridium botulinum cook”, FDA 21 CFR 108 (USA)
- **Milk Pasteurization**: Codex Alimentarius (CAC/RCP 57-2004) CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS. The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not constitute a significant health hazard. "As C. burnettii is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of C. burnettii in whole milk (4% milkfat)."
- **Almond Processing** (USA): 7 CFR 981.442 USDA (minimum 4-log reduction of Salmonella bacteria in almonds)
- **Nuts Processing** (USA): GMA “Industry Handbook for the Safe Processing of Nuts” (recommendations for a 5 log reduction of Salmonella bacteria on nuts)
- **Juice Processing** (USA): Guidance for Industry: Juice HACCP Hazards and Controls Guidance (The 5-log pathogen reduction requirement in 21 CFR 120.24.)
- **Egg Processing**: International Egg Pasteurisation Manual
And beyond…Further Literature

Issues To Consider When Setting Intervention Targets with Limited Data for Low-Moisture Food Commodities: A Peanut Case Study

(Schaffner et al.; 2013; JFP 76(2): 360-369)

compare various assumptions about prevalence and concentration and how they are combined. The discussions made clear that data and risk models developed for other low-moisture foods like almonds and pistachios may be applicable to peanuts. Workshop participants were comfortable with the \textit{use of a 5-log reduction for controlling risk in products like peanuts} when the level of contamination of the raw ingredients is low (<1 CFU/g) and the process well controlled, even when limited data are available. The relevant stakeholders from the food safety community may eventually conclude that as additional data,

generally supportive of the effectiveness of a 5-log reduction, based on both a consideration of microbiological risk assessment concepts and the past use of such a requirement to protect public health.
Process Considerations (Control measure)

- Identify the **steps that are most effective or most likely to control the hazard** in the process and over shelf-life of the product;

- Understand the **principle of action** at each step (e.g. heat, pressure, electrochemical treatment);

- Evaluate **potential for recontamination after the control step**;

- Evaluate **potential for growth** of the pathogen of concern in the product
Example – Cocoa Production

- Raw cocoa beans
  - Pre-cleaning
    - Debacterisation
      - Roasting
        - Breaking & Winnowing
          - Drying
            - Raw cocoa nibs
              - Alcalization
                - Roasting
                  - Grinding
                    - Cocoa Liquor
                      - Pressing
                        - Cocoa Powder
                      - Cocoa Butter
                        - Steam
                          - Water
Principle of Action

Thermal Interventions - **Heat transfer** to products:

- **Conduction** (solid)
- **Convection** (liquid / gas)
- **Microwave** (di-polar molecular oscillations)
- **Radiofrequency** (friction by molecular movements of charged molecules)
- **Ohmic heating** (direct electrical excitation)
**Principle of Action**

**Non-thermal Interventions e.g.**

- Pulsed Electric Fields
- Gas Treatments
- UV
- High Pressure processing
- Filtrations

---

**Table:**

<table>
<thead>
<tr>
<th>Processing Technique</th>
<th>Parameters</th>
<th>Microbial target and mode of action</th>
<th>(Food) Applications</th>
<th>Considerations</th>
<th>Limitations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Hydrostatic Pressure (HHP)</td>
<td>Pressure, temperature, time</td>
<td>Vegetative bacteria, fungi, viruses, Membrane damage, protein denaturation, decrease intracellular pH</td>
<td>Solids and liquids, batch and continuous processes, 100-1000 MPa</td>
<td>Lower $a_t$ protects cells, and low pH enhances inactivation. Effective at ambient, cooling and freezing temperatures. Exponentially growing cells more sensitive than stationary phase cells, cocci more resistant than rods. Gram positive organisms more resistant than Gram negative. Some viruses highly resistant. Bacterial spore resistance (&gt; 1000 MPa). Assists thermal inactivation of spores by rapid adiabatic heating, or requires additional factors for control of bacterial spores e.g. low pH, and/or low $a_t$ and/or refrigeration temperatures.</td>
<td>Higher cost than heat treatment. Difficult operation. The $a_t$ of the low $a_t$ foods needs to be increased before treatment and consequently lowered by a drying step after treatment.</td>
<td>Source: Ceylan et al, 2021; Acuzelleg, 2015; Barba, Koubaa, do Prado-Silva, Crippen, &amp; de Souza Sant’Ana, 2017; Garriga, Grebol, Ayres, Monfort, &amp; Hugas, 2004; Ernsten et al., 2010; Lado &amp; Yousef, 2002; Potter et al., 2017; Shigelusa, Ohnomori, Sato, Tajima, &amp; Hayashi, 1991; Smelt, 1998; Syed, Buffa, Guanis, &amp; Saldo, 2016; Yuan, Lu, Lu, Tang, &amp; Ge, 2017</td>
</tr>
</tbody>
</table>
How good do you know your process?

Which parameters need to be considered to control a given hazard?

- **Moisture** (Steam, Water additions)
- **Time** (Speed, Type of material flow – laminar – turbulent)
- **Temperature** (even distribution / cold spots)
- **Pressure / Gas / Irradiation**
- **Weight**
- **potential others** (instrument specific)
How good do you know your product?

Intrinsic Product Characteristics and their variability:

- Moisture / Water Activity
- Composition: Fat / Protein / Sugar / Salt / Preservatives
- pH
How good do you know your product?

Physical Product Characteristics and their variability:

- Density / Size
- Surface
- (Initial ingoing temperature)
- Initial Form (e.g. raw or pre-processed)
- Final Form (e.g. pieces, whole, pastes)
Heat resistance Comparison of various bacterial pathogens

Source: Ceylan et al, 2021
Summary - Process

Is it...

Understood: Principle of Action (technical drawings)

Described: Operational Procedures & Limits

Controlled: Process capability & Variability

Reproducible: Trend Analysis shows no drift
Summary - Product

Product variables like

- fat / sugar / salt
- antimicrobial Compounds
- water activity / moisture
- sizes / surface / density
- Temperature
Thank you for your attention!
Running a Process Validation Study

Roy Betts
Running the study- the start

- Never start running the study before you know:
  - What you want to achieve- microbiologically:
    - Target organisms you are aiming to eliminate.
  - Process objective you want to achieve (i.e. log kill).
  - Your product parameters- anything important to the process: pH, aW, fat, oil, protein, portion size, particle size, volumes of liquids & viscosity in pack etc. and their critical limits.
  - The process equipment being used and its operating characteristics
What’s worst Case

• Always validate under worst case conditions.
• Worst case considerations?
  • Lowest aW
  • Highest fat
  • Largest pack/particulate size
  • Most viscous
  • Coolest points in process
  • Shortest process time
So now we validate!

• How?
  • In-plant validation
  • Laboratory or Pilot scale study
<table>
<thead>
<tr>
<th>Laboratory/Pilot Plant</th>
<th>In Plant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathogens may be used</td>
<td>Surrogates must be used</td>
</tr>
<tr>
<td>Death data relates to pathogens</td>
<td>Death data relates to surrogates</td>
</tr>
<tr>
<td>Careful control of process parameters in lab equipment</td>
<td>Process parameters from actual equipment to be used in manufacture</td>
</tr>
<tr>
<td>Flexibility in inoculation of organism-material use is small</td>
<td>Inoculation adapted to product/process/pack—material use is large</td>
</tr>
<tr>
<td>Flexibility in lab use</td>
<td>Trial fitted into a production schedule—full clean needed after trial</td>
</tr>
<tr>
<td>Data must be interpreted for In-plant comparability</td>
<td>No interpretation needed—the production plant was used</td>
</tr>
</tbody>
</table>
Validation - things you must do

- Equipment: serviced, calibrated—working correctly
- Inoculum: matched/adapted to product characteristics
- Inoculation:
  - realistic position,
  - volume,
  - no change to product characteristics,
  - inoculum level- will depend on process objective- but 2 logs higher than kill required
- Location to do product inoculation—where?
  - Transport to process facility
  - Maintenance of inoculum viability
How much do I need to do?

- Replication must be done.
- The more variability in the process, the more replication is needed.
- Replication: independent batches product / inoculum
- Lethality studies: 3 samples at each time point
- End point studies: 5 to 10 samples
- Enough replication to give confidence in the results
- Controls always needed
- Remember- you won't do this very often- safety depends on it- make it good.
Placing samples in line

- Introducing samples to the line
  - Where & how
  - Realistic
- Effect of sample holders on the process
  - If sample holders used - do they effect process
Collection of the processed material

• At the end of the normal process.
• Minimise changes to microbial numbers
• Transport to laboratory quickly
• Laboratory work to be done immediately

• Clean up the process environment
• Audit equipment taken in and brought out
• The validation must have no adverse effect on subsequent normal production
Laboratory work

- Use recognized methods
- Recovery methods - organisms may be injured
- Selective media will not allow injured organisms to recover
- Test for inoculated organisms alone, or other background flora as well?
- Collect all data in preparation for data analysis
Revalidation?

• Once its done, its done?
  • But how long does validation last.
  • When does validity run out
• For validation to remain valid-
  • all equipment being used must remain constant- calibrated, serviced.
  • Operating exactly the way it was during the validation exercise
• Any change to equipment, product flow, methods of operation etc. has to be reviewed to assess if revalidation is required.
• Even if it is believed all remains the same, it would be prudent to revalidate at regular intervals
Roy Betts

Campden BRI
food and drink innovation
Obtaining scientific evidence and data evaluation for process validation

Heidy den Besten
Evidence

Observational data: challenge study – worst case scenario
lab scale testing with pathogens
in process: indicators or surrogates
Evidence

Observational data: challenge study - worst case scenario
lab scale testing with pathogens
in process: indicators or surrogates

Scientific data: support design validation study
representativity, variability, data bases, meta-analysis
Scientific data collection

- Historical validation data
- Scientific literature
- Microbiological risk assessments – WHO, FAO, governmental agencies
- Data bases – Combase
Meta-analysis

systematically compile and analyze a large collection from available in-house data, published studies or databases aiming to produce a global estimate of the parameter(s) of interest and its variability

• Points to dominant factors that influence parameter(s)
• Quantifies variability
Kinetic parameters for heat resistance

1 log 1 log

log cfu/ml

D

time

log D

1 log

Z

Temp
Non-linear inactivation

- Methodology artifacts?
  e.g. shoulder curvature due to cell clumping
- Counts above detection limit?
Non-linear inactivation

- Weibull model with shape parameter

\[ \log N_t = \log N_0 - \left( \frac{t}{\delta} \right)^\beta \]

Mafart et al., 2002
Non-linear inactivation

• Weibull model with shape parameter

\[
\log N_t = \log N_0 - \left( \frac{t}{\delta} \right)^\beta
\]

Mafart et al., 2002

• Reparameterized model to model target reduction (e.g. 6-log)

\[
\log N_t = \log N_0 - 6 \left( \frac{t}{6D} \right)^\beta
\]

Aryani et al., 2015
Variability in heat resistance *L. monocytogenes*

- Low $a_w$ products: $z = 9.2^\circ C$
- Various products: $z = 7.0^\circ C$

940 $D$-values

Van Asselt et al., 2006
**Product level** *L. monocytogenes*  

milk only  

\[ z = 6.2 \, ^\circ\text{C} \]  

226 \text{ D-values}  

Den Besten et al., 2012
Extrapolation: be careful

<table>
<thead>
<tr>
<th>Product group</th>
<th>n&lt;sup&gt;a&lt;/sup&gt;</th>
<th>z-value (°C)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Temperature range &lt;i&gt;D&lt;/i&gt;-values (°C)</th>
<th>&lt;i&gt;D&lt;/i&gt;&lt;sub&gt;60&lt;/sub&gt; (min) average</th>
<th>&lt;i&gt;D&lt;/i&gt;&lt;sub&gt;72&lt;/sub&gt; (s) average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Various products except those with low &lt;i&gt;a&lt;/i&gt;&lt;sub&gt;w&lt;/sub&gt;</td>
<td>940</td>
<td>7.0</td>
<td>48-79</td>
<td>2.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Products with low &lt;i&gt;a&lt;/i&gt;&lt;sub&gt;w&lt;/sub&gt;</td>
<td>27</td>
<td>9.2</td>
<td>56-68</td>
<td>18.3</td>
<td>55</td>
</tr>
<tr>
<td>Milk</td>
<td>226</td>
<td>6.2</td>
<td>50-75</td>
<td>2.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Broth</td>
<td>372</td>
<td>5.2</td>
<td>55-70</td>
<td>1.5</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Available data could be out of range of actual situation – use with caution

Ceylan et al., 2021
Variability in inactivation strain variability

$L.\ monocytogenes$

Experimental

2 technical duplicates

Aryani et al., 2015
Variability in inactivation strain variability

$L.\ monocytogenes$

Experimental

Biological

3 biologically independent reproductions

Aryani et al., 2015
Variability in inactivation strain variability

*L. monocytogenes*

- Experimental
- Biological
- Strain

20 strains

Aryani et al., 2015
Variability in heat resistance *L. monocytogenes*

Van Asselt et al., 2006
Benchmarking

20 *L. monocytogenes* strains

$z = 5.2°C$

Use robust strain for challenge tests
Data analysis 5 log reduction reached?
**Data analysis 5 log reduction reached?**

\[ \text{Deterministic}_{\text{Reduction}} = \text{mean}(N_0) - \text{mean}(N_f) \]

<table>
<thead>
<tr>
<th>Replicate</th>
<th>( N_0 )</th>
<th>( N_f )</th>
<th>Deterministic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.04</td>
<td>3.24</td>
<td>5.00</td>
</tr>
<tr>
<td>1</td>
<td>8.08</td>
<td>2.71</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7.90</td>
<td>3.07</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8.23</td>
<td>3.44</td>
<td>4.93</td>
</tr>
<tr>
<td>2</td>
<td>8.39</td>
<td>3.52</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8.13</td>
<td>3.01</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7.92</td>
<td>2.52</td>
<td>5.19</td>
</tr>
<tr>
<td>3</td>
<td>8.07</td>
<td>2.92</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7.83</td>
<td>2.81</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.04</td>
<td>0.14</td>
</tr>
</tbody>
</table>
Data analysis: 5 log reduction reached?

$$\text{Deterministic}_\text{Reduction} = \text{mean}(N_0) - \text{mean}(N_f)$$

<table>
<thead>
<tr>
<th>Replicate</th>
<th>$N_0$</th>
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<tr>
<td>1</td>
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<td>2.81</td>
<td></td>
</tr>
</tbody>
</table>

| Mean     | 5.04  |
| SD       | 0.14  |

...... but we have to consider the variability.
Data analysis: 5 log reduction reached?

\[ MRC_{Reduction} = \min(N_0) - \max(N_f) \]

<table>
<thead>
<tr>
<th>Replicate</th>
<th>( N_0 )</th>
<th>( N_f )</th>
<th>Deterministic Reductions</th>
<th>Minimal Reduction Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.04</td>
<td>3.24</td>
<td>5.00</td>
<td>4.66</td>
</tr>
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<td></td>
<td>5.04</td>
<td>4.73</td>
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<td>SD</td>
<td></td>
<td></td>
<td>0.14</td>
<td>0.16</td>
</tr>
</tbody>
</table>
In conclusion

• Available scientific data is useful to support the design of a validation study
In conclusion

• Available scientific data is useful to support the design of a validation study
• But available data and actual situation often does not match perfectly - and this is often being most difficult to decide
• Challenge test is often required to prove sufficient reduction
• Variability (strain, batches, replicates, samples) should be addressed
Guidance on validation of lethal control measures for foodborne pathogens in foods

Erdogan Ceylan¹ | Alejandro Amezquita² | Nathan Anderson³ | Roy Betts⁴ | Laurence Blayo⁵ | Francisco Garces-Vega⁶ | Elissavet Gkogka⁷ | Linda J. Harris⁸ | Peter McClure⁹ | Anett Winkler¹⁰ | Heidy M. W. den Besten¹¹
collaboration

common challenges

science

communicate & disseminate

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Comprehensive Reviews in Food Science and Food Safety

International Life Sciences Institute

Risk Assessment and Control Options in Food Processing
Organised by the Microbiological Food Safety Task Force
Save the date: 12 November 2019
16.00-17.00 CET, 9.00-10.00 EST
Contact Information

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• Roy Betts, Roy.Betts@campdenbri.co.uk
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This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.

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