



Produced by  
**FoodSafety**  
magazine™

# Process Validation Considerations

Nathan Anderson, Ph.D.

Director, Div. Food Processing Science & Technology



---

Human Foods Program

# Validation of Preventive Controls



Source: FBM Machines, Inc.  
<https://fbmbakingmachines.com/ovens/bell-5/#>

- Preventive controls should be implemented when pathogens in low moisture foods pose a risk.
- **Preventive controls need to be validated.**

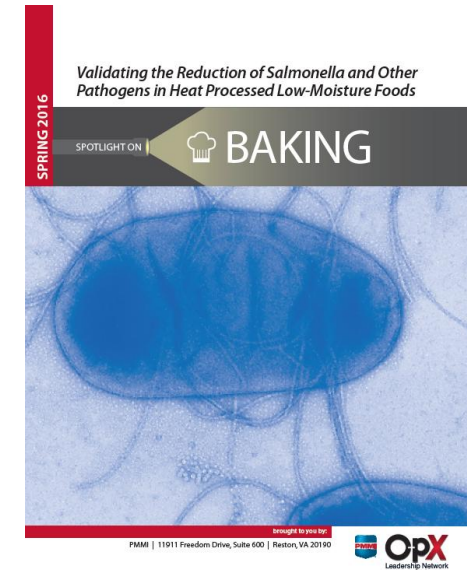
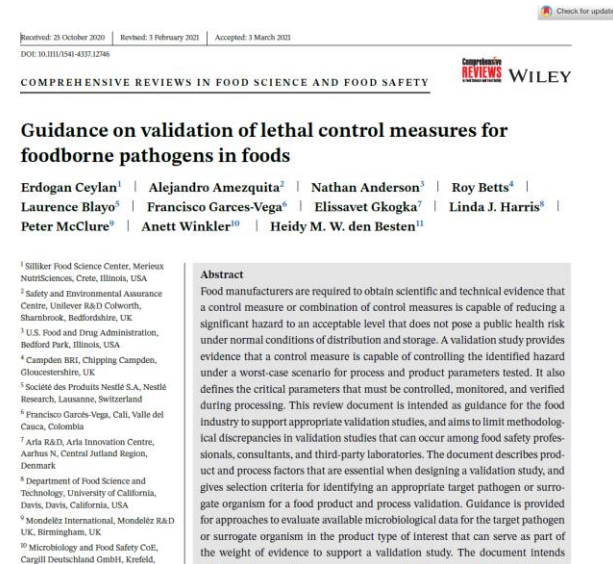
*\*Not all foreseeable hazards for a food require a preventive control in all facilities.*

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry

# Approaches to Validation

- Government guidance
- Safe harbors
- Published scientific literature
- Mathematical models
- Data from previous studies
- Data from new scientific experiments
- Any combination of these approaches

*Exceptional lethality*



FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

# Government Guidance

Guidance for industry: Juice hazard analysis critical control point hazards and controls guidance, first edition. Juice HACCP (FDA, 2004)

Fruit juices (pH 4.0 or less) 160°F (71.1 ° C) for 3 s  
(5-log reduction of *E. coli* O157:H7, *L. monocytogenes*, *Salmonella*)

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first>

# Safe Harbors

## Oil Frying (Almonds/*Salmonella*)

- $\geq 260^{\circ}\text{F}$  ( $127^{\circ}\text{C}$ ) for  $\geq 2.0$  min ( $\geq 5$  log)
- $\geq 260^{\circ}\text{F}$  ( $127^{\circ}\text{C}$ ) for  $\geq 1.6$  min ( $\geq 4$  log)

## Blanching (Almonds/*Salmonella*)

- $\geq 190^{\circ}\text{F}$  ( $87.8^{\circ}\text{C}$ ) for  $\geq 2.0$  min ( $\geq 5$  log)
- $\geq 190^{\circ}\text{F}$  ( $87.8^{\circ}\text{C}$ ) for  $\geq 1.6$  min ( $\geq 4$  log)



april 2007

### Guidelines for Validation of Oil Roasting Processes

#### Overview

Oil roasting is one of the thermal processes that are used by the almond industry and manufacturers to make roasted almond products. Dr. Linda Harris of the University of California at Davis (UCD) studied the efficacy of hot oil on the reduction of *Salmonella* on almonds in a hot oil bath (ABC Supporting Document DOC003). Based upon the information from that study, the ABC Technical Expert Review Panel (TERP) determined that a minimum process of 2.0 minutes of exposure to hot oil at  $260^{\circ}\text{F}$  or above will provide a 5-log reduction of *Salmonella* on the surfaces of whole almonds.

Subsequently, the US Food and Drug Administration (FDA) reviewed the information and issued a Letter of Determination to acknowledge this process as a pasteurization process for almonds (ABC Supporting Document DOC005). Almond products processed under those conditions may be labeled as pasteurized.



april 2007

### Guidelines for Validation of Blanching Processes

#### Overview

Blanching is a thermal process that is used by almond processors to remove almond skins. Dr. Linda Harris of University of California at Davis (UCD) studied the efficacy of hot water on the reduction of *Salmonella* on almonds in a hot water bath (ABC Supporting Document DOC002). Based upon the information from that study, the ABC Technical Expert Review Panel (TERP) determined that a minimum process of 2.0 minutes or more of exposure to hot water at  $190^{\circ}\text{F}$  or above will provide a 5-log or greater reduction of *Salmonella* on almonds.

Subsequently, the US Food and Drug Administration (FDA) reviewed this information and issued a Letter of Determination to acknowledge this process as a pasteurization process. Almond products processed utilizing those conditions may be labeled as pasteurized. (ABC Supporting Document DOC005)

# Published Scientific Literature

*(same parameters on same product and process)*

- > 5 log reduction achieved

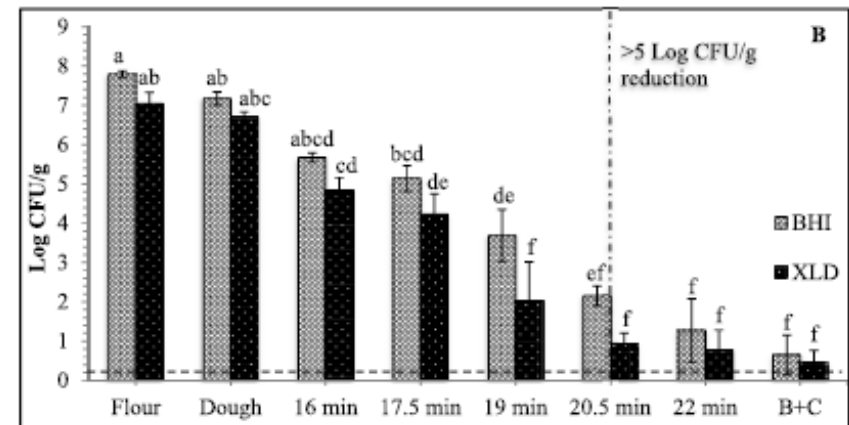
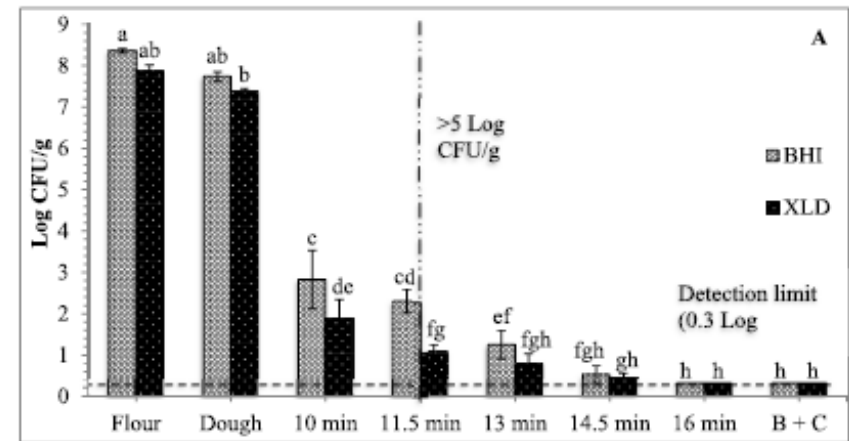
*Hard Cookies*

- After 11.5 mins at 185°C (365°F)

*Soft Cookies*

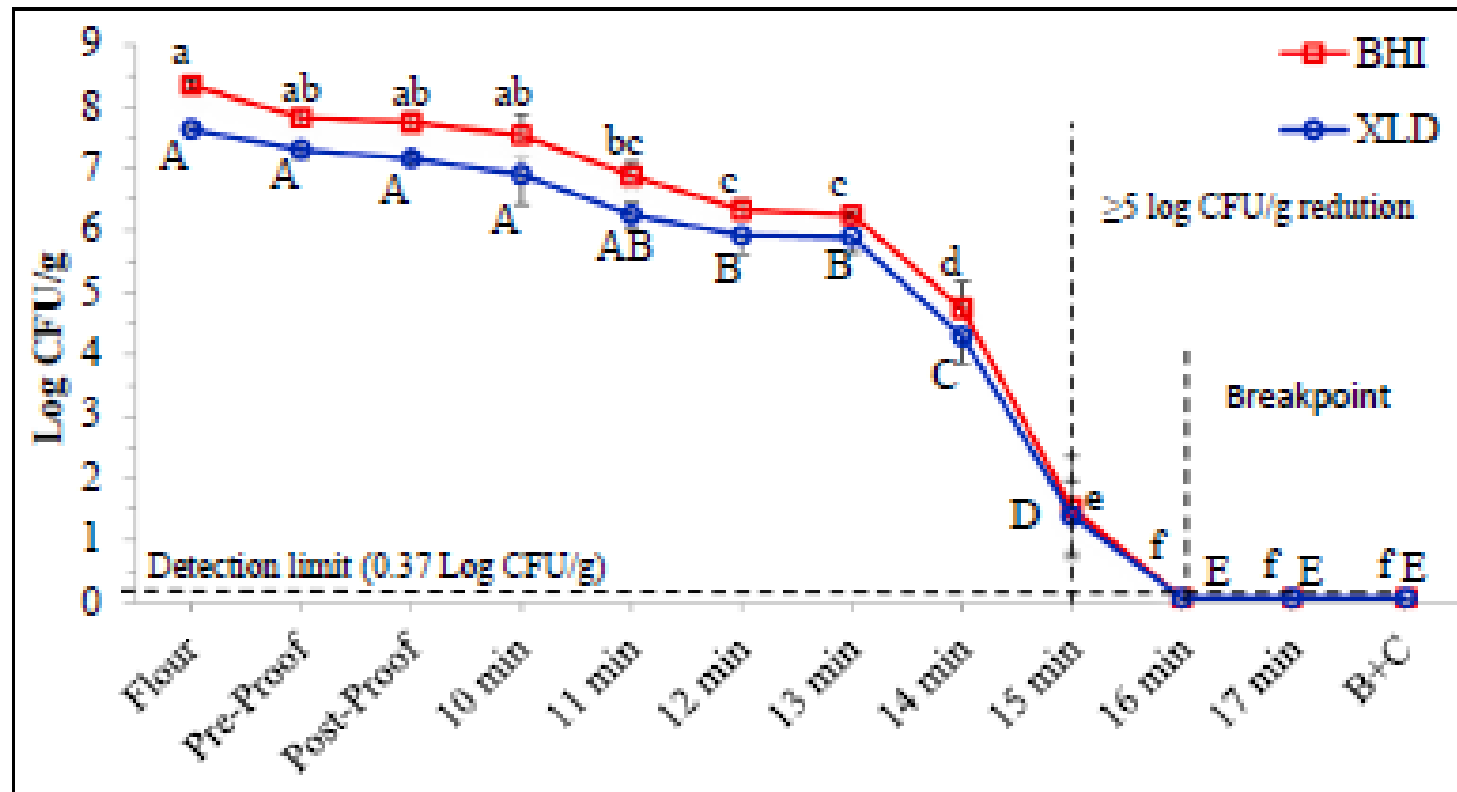
- After 20.5 min at 165.6°C (330.1°F)

(Channaiah et al. 2021)



# Whole Wheat Bread

> 5 log reduction achieved after 15 mins at 190.6°C (375°F)



(Channaiah et al. 2019)

# Toppings, Inclusions & Fillings

## Log reductions achieved

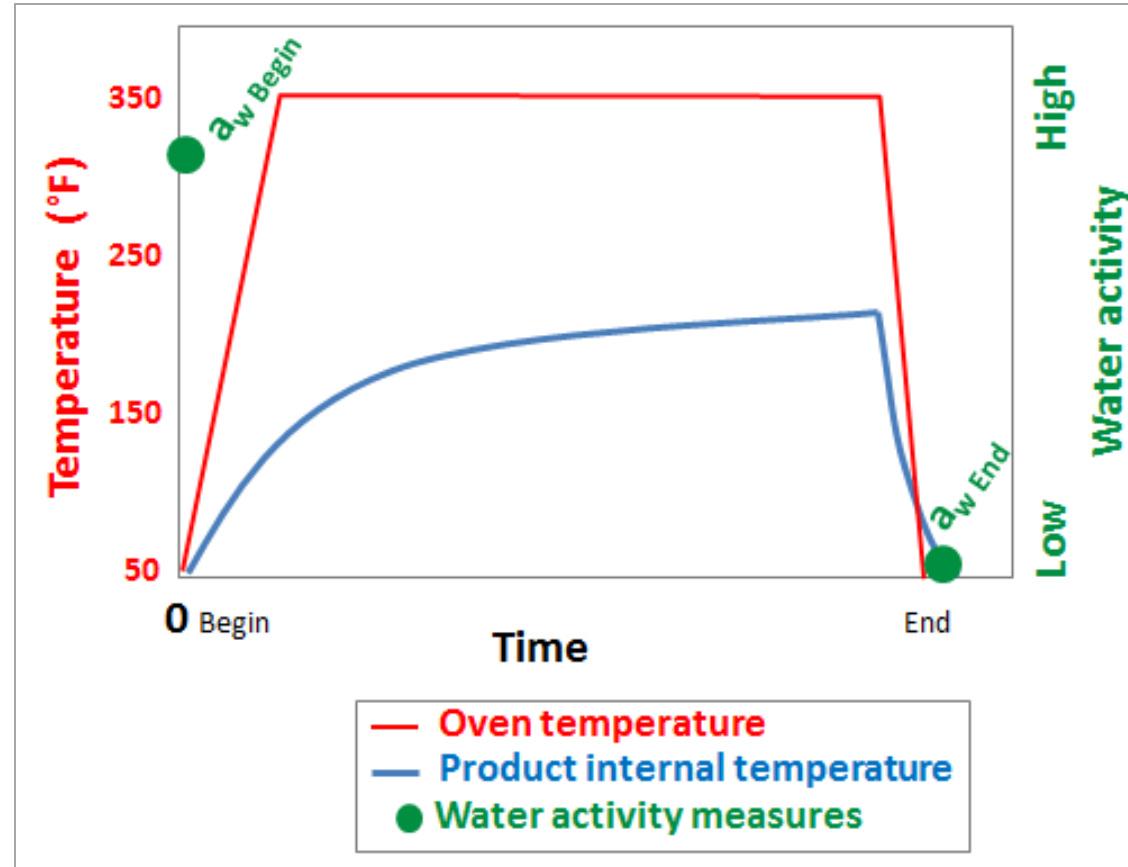
- Baked to match “bun color” standard
- 7 mins at 204°C (400°F) low (3%) RH
  - **>5 log reduction for plain buns**
  - **3.5 log reduction for Sesame topped buns**
- 9 mins at 177°C (350°F) high (20%) RH
  - **> 7 log reduction by 4.5 mins w/ and w/out seeds**
- Baked to “bun-color standard”
- Demonstrated the importance of humidity in the oven



(Shrestha et al., 2016)

# Mathematical Modeling – Baking Process

- Product  $a_w$  known for the beginning and end of this baking process.
- Oven temperature
- Product internal temp.



(Lucore et al., 2017; OpX  
Spotlight on Baking, 2012)

(Courtesy Lisa Lucore)

# Data from Experiments



## Benchtop

- Is it possible to mimic the production process on a laboratory scale?

## Pilot-Scale

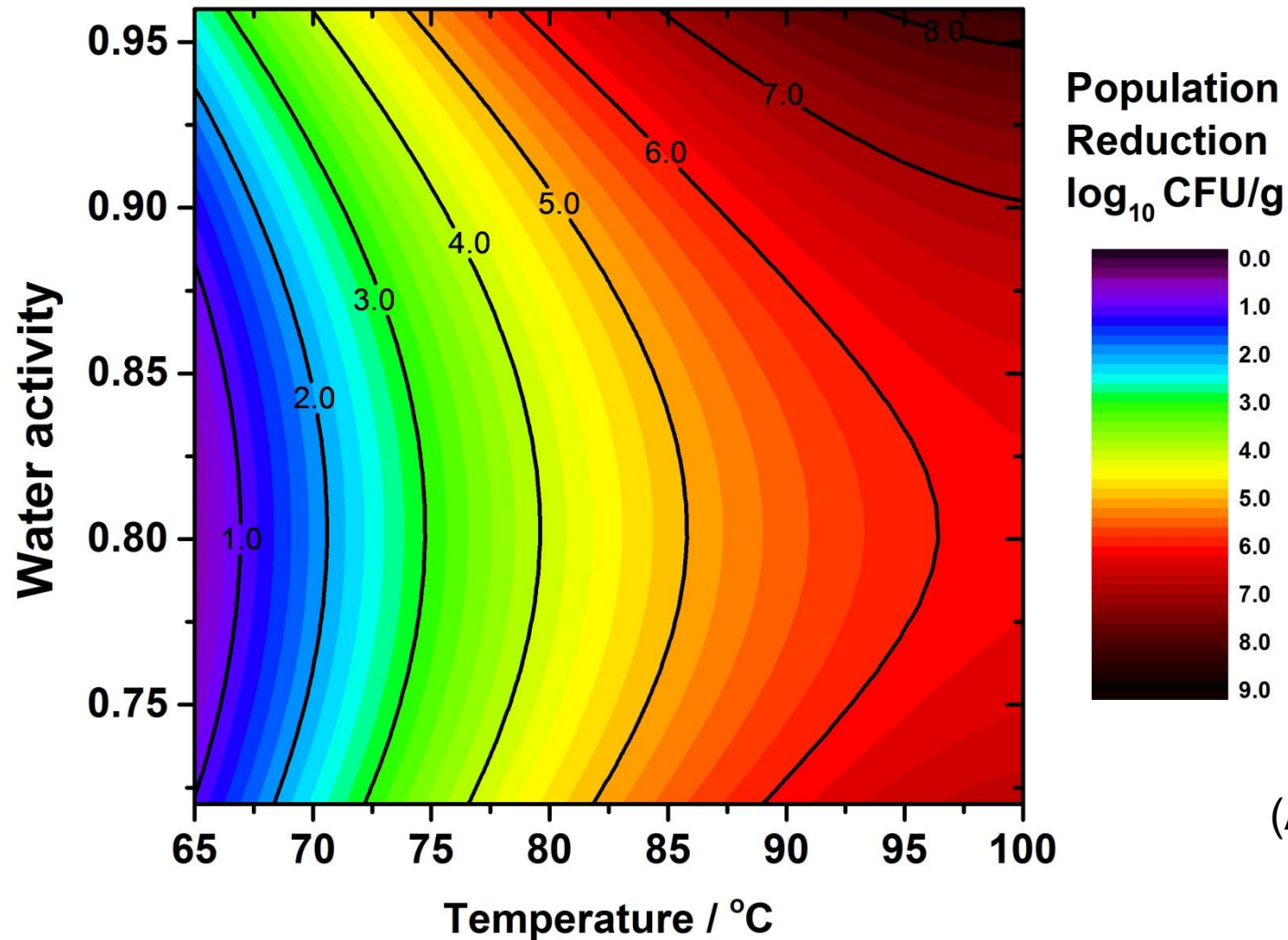
- Is it possible to mimic the production process on a pilot scale?

## In-plant

- Perform in plant validation study using surrogates

(den Besten et al., 2020)

# Minimum Conditions to Achieve a Target Reduction of *Salmonella* for Extrusion



(Anderson et al., 2017)

# Exceptionally Lethal Processes

“Some food products can only be produced using **exceptionally lethal processes** that adequately control biological hazards. If the processing is not conducted in a way that adequately controls biological hazards, the product would not be suitable for distribution.”

Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

# Exceptionally Lethal Processes

- “Due to the exceptional lethality of the processes SMEs may not identify any known or reasonably foreseeable (“potential”) biological hazards.”
- “Alternatively, identify vegetative pathogens as known or reasonably foreseeable (“potential”) biological hazards but determine that they do not require a preventive control because the process is exceptionally lethal.”

Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

# Example Exceptionally Lethal Processes

## Caramel

- Boil ingredients for several minutes to about 240°F (116°C)
- Without boiling for several minutes, the ingredients will not result in a chewy caramel when cooled.

## Jam, Jelly, or Chutney

- Boiling would provide exceptional lethality for biological hazards (e.g., *E. coli*, *Salmonella*, and *Listeria monocytogenes*)
- Without boiling these products will not thicken to the desired consistency.

Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

# Example Exceptionally Lethal Processes

## Fruit cocktail

- Designed to inactivate sporeformers >>> greater heat resistance than vegetative pathogens.

## Gravy

- A process of making a gravy by boiling or cooking down a liquid sauce to thicken it would provide exceptional lethality for vegetative pathogens

Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

# Example Exceptionally Lethal Processes

## Snack Crackers

- Bake at 482°F (250°C) for 4.5 min.
- Without this high temperature process, the baked and cooled product would not have or retain the characteristic texture desired for this snack item.

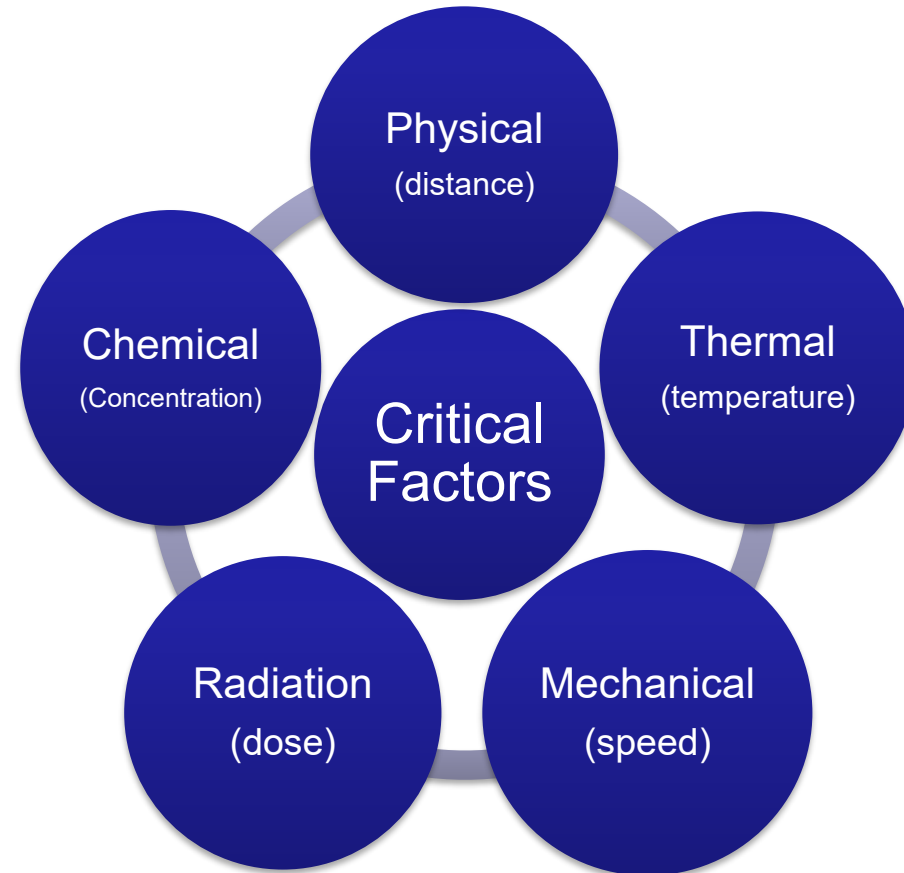
Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

# Processing System

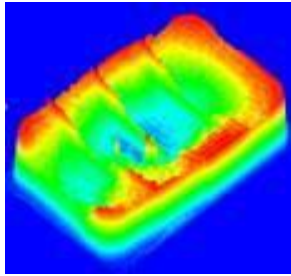
**Does the process effectively control the hazard?**

**What is the mode of inactivation?**

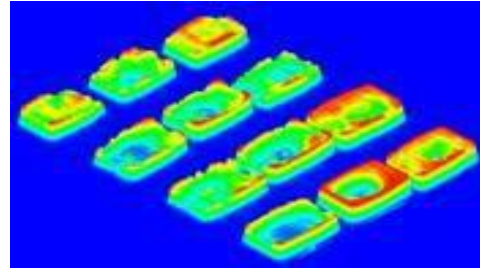
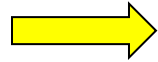
**What are the critical factors?**



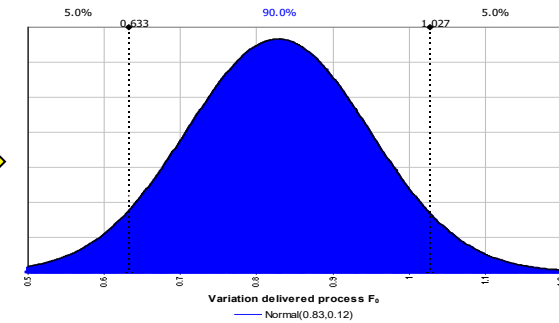
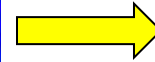
# Process Variability



Temperature variation within the package



Temperature variation within the batch



Process variability

(Thermal images courtesy of Dr. Juming Tang, Washington State University)

# Often *Over-looked* Worst-Case Scenarios

- Interactions between multiple control measures
- Min/Max values for the control measure
- System startup (ramp-up) and shutdown
- Permitted manual operations
- System capacity vs. loading
- Motion/speed of conveying systems

# References

Anderson, N.M., Keller, S.E., Mishra, N., Pickens, S., Gradl, D., Harter, T., Rokey, G., Dohl, C., Plattner, B., Chirtel, S. and Grasso-Kelley, E.M. (2017), Salmonella Inactivation During Extrusion of an Oat Flour Model Food. *Journal of Food Science*, 82: 738-743. <https://doi.org/10.1111/1750-3841.13629>

Appendix 1: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

Ceylan, E. et al. 2021. Guidance on validation of lethal control measures for foodborne pathogens in foods. *Comprehensive Reviews in Food Science and Food Safety*, 20(3), pp.2825-2881. <https://doi.org/10.1111/1541-4337.12746>

FSPCA <https://www.fspca.net/>

OpX Spotlight on Baking <https://pmmiopx.org/work-products/spotlight-on-baking>

# Exceptional Lethality: Perspectives and Pragmatic Application

Matthew Van Natter

Associate Director Global Food Safety, Mars Snacking/Kellanova

Food Safety Summit, May 13, 2026

**MARS**  
SNACKING

Inspiring Happiness  
with Better Snacks  
for Better Days®



**Content, comments and perspectives provided are the opinion of the speaker and do not constitute a Mars Snacking/Kellanova position or requirement.**

# Agenda



**Perspective**

**Application to foods**

**Justification**

**Practical Application**

# Perspective on Exceptional (Abundant) Lethality

# Historical Nature

# Preventive Controls

## Common Foods with Bacterial Lethality Rarely Questioned

- Baked Bread
- Tortilla's
- Cookies

## Example: Cooking Pasta

- Validation demonstrates that temperatures during cooking (boiling for x time) to achieve correct texture exceed those needed to destroy pathogens



# Preventive Controls and HACCP

## Aligning to these principles

- Some products may be measured to create a CCP or Process CP, but not all
- Most products are difficult to measure temperatures in real time
  - Too thin for probes
  - Small – loose heat before testing
  - Process – may have cooling to prevent over toasting
  - Impractical based on equipment/food

NEED: Ongoing assurance that image meets inactivation of target pathogen(s) to produce a safe food

# **Application of Exceptional Lethality to Food Types**

# Can Exceptional Lethality Apply to my Food Types?

## Factors to consider at a minimum:

- Is the maximum amount of the target pathogen(s) able to be determined for the food/mix/WIP/ingredient(s) being processed?
- Can the log kill be measured or accurately calculated from processing data?
- Are significantly more numbers than the maximum amount of target pathogen(s) reduced as measured or calculated as part of processing to meet image of the process?
- Is the image reliable and repeatable, with log reduction occurring at the same or more than calculated/measured amount of target pathogen(s)? (Worst Case Identified?)

Would this type  
of food be  
acceptable for  
application of  
process  
Exceptional  
Lethality?

 **USDA Food Safety & Inspection Service**   
@USDAFoodSafety

Don't sacrifice safety for convenience! Chicken Cordon Bleu may appear ready-to-eat but could still be raw. Read the label, follow cooking instructions, and trust only a food thermometer to tell you it's done – 165 F. Savor every bite safely! [#CordonBleuDay](#)

 Food Safety and Inspection Service  
U.S. DEPARTMENT OF AGRICULTURE

**Safety Tip:**  
Breaded stuffed raw chicken products are pre-browned and may appear cooked, but the chicken is raw.

Follow the label's cooking instructions and use a food thermometer to ensure it reaches 165 F.

ALT 

# **Justifying Exceptional Lethality for a Food**

# Creating a Case or Justification or Application of Exceptional Lethality to a Food

1. **Identify target pathogens for the food/process and what levels those may exist**
2. **Measure process to confirm log reduction**
  - **Inoculation studies - Pathogen of concern or surrogate**
  - **Modeling based on prior studies**
    - **Studies must be applicable to your foods**  
e.g Hot dog processing ≠ cracker process  
e.g. Pancakes ≠ Potato Chips

# Creating a Case or Justification or Application of Exceptional Lethality to a Food

3. Define what you consider Exceptional Lethality for the food / process to adequately inactivate/reduce pathogen population
  - Consider 2x the highest potential bacterial load of the hardest to kill target pathogen
  - e.g. 4 log Salmonella spp. as a target organism in Rolled Oat, and 8 log as excessive lethality.
4. Must be able to demonstrate that the conditions required to meet image far exceed the processing required to mitigate those hazards

# **Creating a Case or Justification or Application of Exceptional Lethality to a Food**

**5. Document your assumptions, parameters, conclusions!!!**

**Must show your work for:**

**Audits**

**Regulatory Inspection**

**Justifications**

# **Practical Application of Exceptional Lethality**

# Foundational Elements

## Must have PRPs in Place and Consider Management Components

Post Process contamination must not be in place after the lethality step and must have proper operational sanitation, GMPs, process controls, and start of run sanitation to maintain the environment and prevent cross contamination

Have a Verification that the process step removes the hazard (temperatures in model, process verification that settings are same as model or inoculation, as well as a Validation of the study (Model or Inoculation) - This links the science in your justification to your HACCP or Food Safety plan.

# **Documenting Identification and Mitigation of Hazards by Exceptional Lethality**

## **Facility or Process Line HACCP or Food Safety Plan**

**Must identify pathogen hazards in IHA/PHA as same that your justification for Exceptional Lethality is defined**

**Must be able to discuss operational parameters and measured as meeting the conditions for demonstrated in the justification and/or validation**

**HACCP / Food Safety Plan needs to provide where the inactivation takes place**

# Quick Example

## Food Safety Plan

### IHA:

**Salmonella spp. potential in incoming ingredient(s)**

### PHA:

**Step 1: Mixing raw ingredients with *Salmonella spp.***

**Step 2: Form and Bake – Survival of *Salmonella spp.* after baking is low/no risk**

### Justification:

**Study demonstrates that Baking process to achieve image food will inactivate 2x the maximum log amount of *Salmonella spp.* in formed mix/WIP and survival of the pathogen is not possible after the bake step**

# **Operational Gains for Processing a Food with Exceptional Lethality**

**May make case to not have a CCP or Process Preventive Control at this step**

- **Enables process to be represented for items that may have difficulty for measurement (e.g. cracker or wafer)**
- **Enables operators to focus on CCPs other than bake/cook steps**
- **Reduces potential risks from measurement or paperwork issues, causing business delays/cost**

**Process controls must be in place that if failures occur where product doesn't meet image, the food will be destroyed and the line reset to hygienic conditions**

# **Prepare to Explain, Show Evidence and Educate**

## **Bringing Others on a Journey to Understand**

- **New concept for most – Discuss the science**
- **Regulatory and 3<sup>rd</sup> party certifying bodies need may need to resources to see how this fits within framework (e.g. CCP or PC requirement vs science/evidence)**
- **Team needs to be educated on how to present**
- **Operators should understand corrective actions to bring back into control when image isn't met**

# Parting Thoughts

**Exceptional Lethality may apply to foods in production and an approach to explaining and may streamline work for FS compliance**

**Need to justify your decisions to use the concept of Exceptional Lethality**

**May still want a Verification that the process step removes the hazard, as well as a Validation of the study (Model or Inoculation) – Show the science**

**Bring your Inspectors and Auditors on the journey of understanding the topic related to foods produced under Exceptional Lethality**

# Thank you

