

# Kill Step Validation of the Baking Process

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## Outline

- Food safety challenges for bakery products
- Changes with FSMA
- Need for a baking kill step validation
- Foundational KSV research
- Baking Process Kill Step Calculators
- Baking process kill step for flour tortillas
- Show and tell

## Bakery Products: Food Safety Challenges

- In the United States:
  - 2,800 commercial bakeries
  - 6,000 retail bakeries
  - Market value = \$30 billion
- Safe production record if compared to the rest of the food industry (meat or produce)
- Yet, there were 30 disease outbreaks and 706 illnesses related to bakery products from 1998 to 2007



## Bakery Products: Food Safety Challenges

- Pathogens can be introduced into bakery products through a wide range of ingredients:
  - Eggs
  - Milk
  - Flour
  - Dehydrated veggies
  - Flavorings
  - Spices
  - Seeds
- The presence of pathogens in bakery ingredients & products could create a food safety risk if the product is improperly ba





## Bakery Products: Food Safety Challenges

Important definitions

- Microbial Spoilage
- Shelf Life
- Water activity
- Pathogens
- *Salmonella* spp.



## The Need for a Kill Step Validation

- Most food products undergo a supposed kill step at the point of production such as baking, roasting, extruding, or frying
- However, these processes, while intuitively correct, have no scientific proof or validation



## Bakery Products: What Changed with FSMA?

- The Food Safety Modernization Act (FSMA) aims to ensure that the US food supply is “safe” by shifting the focus from
- **RESPONDING** to food safety failures like foodborne disease outbreaks to
- **PREVENTING** the occurrence by requiring both the **VALIDATION** and **VERIFICATION** of all preventive controls steps that are critical for food



## The Need for a Kill Step Validation

- Validation is a scientific evaluation that provides documented evidence that the baking process is capable of consistently ensuring the destruction of pathogenic microorganisms: LETHALITY



## The Need for a Kill Step Validation

- This is often expressed as “log reduction”  
Logarithmic reduction reduces the count of pathogenic organisms by a specific exponent, such as reducing the count from:

$10^6$  (1,000,000 bacterial cells) to

$10^1$  (10 bacterial cells)

This is a 5 Log reduction





## Kill Step Validation Research

AIB International partnered with industry stakeholders and state universities to develop kill step validation (KSV) procedures for various bakery products



## Kill Step Validation Research

Main objectives:

- Develop **KSV** procedures for bakery products
- Develop **Baking Process Kill Step Calculators**
- Provide on-site support & training to comply the **FDA-FSMA's** validation and verification requirement



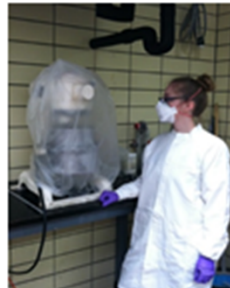
## Foundational Research Project

Validation of baking as a kill step in  
controlling *Salmonella* in hamburger buns



## Research Process

- We worked in an BioSafety Level-2 pilot food processing laboratory
- Trays of wheat flour were inoculated with 3 types of *Salmonella* and *Enterococcus*
- Dough was made



## Microorganisms Used in this Research

- Salmonella is a genus of bacteria that can cause illnesses such as typhoid fever paratyphoid fever and food poisoning (salmonellosis)
- Enterococcus is a genus of bacteria that can coexist in the human intestine, but it may also be pathogenic, causing diseases such as meningitis or endocarditis





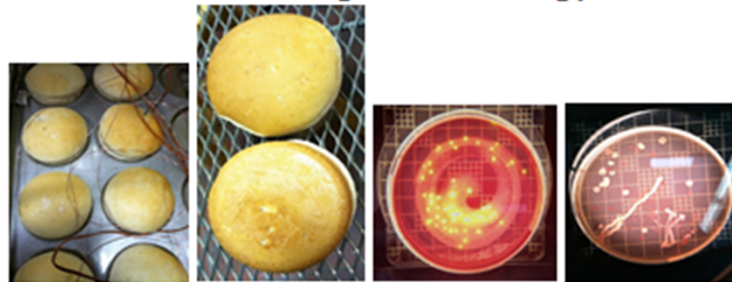
## Research Process

- The dough was kneaded, formed, proofed & baked to mimic commercial manufacturing conditions
- Before placement of the pan in the oven, thermocouples were inserted in the center to record temperature



## Research Process

- After baking and cooling *Salmonella*, *Enterococcus*, and yeast were enumerated with standard testing methodology

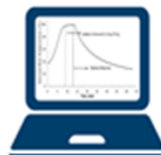


## Baking Process Kill Step Calculator

- Translation of research to commercial application



## Baking Process Kill Step Calculator



Designed to provide bakery manufacturers with a science-based **validation** tool that can be used to demonstrate the effectiveness of a baking process to destroy *Salmonella* in a variety of bakery products to comply with new FSMA regulation



## Baking Process Kill Step Calculator (BPKC)

- How Does It Work?





## Validating the Kill Step

You need 3 components:

1. A data-logger that will register the temperature of the product as it goes through the oven: MOLE or Scorpion, etc.

Temp data obtained  
from data logger

2. A calculator downloaded from the AIB website that calculates the D, Z and T values for the spec

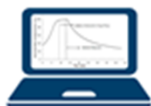
D, Z and T-ref are  
obtained from AIB's  
KSV study

[www.aibonline.org/aibOnline/develop-your-product-solutions/baking-process-kill-step-calculators.aspx](http://www.aibonline.org/aibOnline/develop-your-product-solutions/baking-process-kill-step-calculators.aspx)



## Validating the Kill Step

3. A computer with access to Excel to export the data from the data-logger

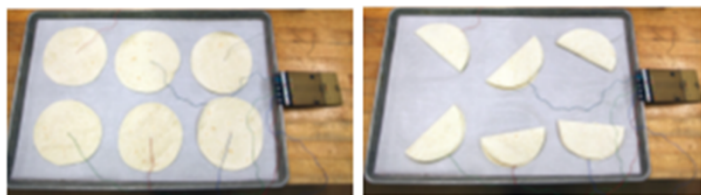


The result:

Baking process lethality for *Salmonella*  
in log values for your specific product

## Validating the Kill Step

A data-logger that will register the temperature of the product as it goes through the oven or in the case of tortillas, once they come out of the oven



[www.aibonline.org/aibOnline/develop-your-product-solutions/baking-process-kill-step-calculators.aspx](http://www.aibonline.org/aibOnline/develop-your-product-solutions/baking-process-kill-step-calculators.aspx)



Secs.	Sensor 1	Sensor 2	Sensor 3	Sensor 4
1	190.9	350.5	211.2	193.5
2	189.8	347.6	209.7	192.6
3	188.9	347.0	208.1	191.6
4	187.9	345.3	206.3	190.4
5	187.1	337.8	205.2	189.5
6	185.9	336.3	203.8	188.3
7	185.2	334.8	202.4	187.4
8	184.7	332.3	201.1	186.4
9	184.1	329.5	198.9	185.3
10	183.4	328.9	197.3	184.1
11	182.2	322.5	196.2	183.0
12	181.4	320.9	194.6	181.9
13	180.4	318.3	193.2	180.6
14	179.7	317.0	191.1	179.7
15	178.9	315.9	188.1	178.4
16	177.6	313.1	186.3	177.4
17	176.3	308.8	184.1	176.1
18	175.3	306.2	182.6	175.0
19	174.1	305.9	181.3	173.8
20	173.4	305.7	180.2	172.8
21	172.1	302.3	179.2	171.6
22	171.1	300.3	177.9	170.5
23	170.2	299.7	177.3	169.3
24	169.6	299.1	177.0	168.0
25	169.2	298.3	176.4	166.6
26	168.5	295.4	174.8	165.0
27	166.8	290.5	173.2	163.7
28	165.6	290.1	170.8	162.2
29	164.3	286.7	169.3	160.6
30	163.7	282.6	168.3	159.3
31	163.0	278.3	167.0	157.7

## Validating the Kill Step

### BAKING PROCESS KILL STEP CALCULATOR: Tortillas

#### Product & Process Specifications:

Facility name & location:

Microorganism:

Salmonella spp.

Product & code:

T<sub>90</sub> (°F):

141.5

Product Description:

Flour

D<sub>90</sub> (min):

4.57

z (°F):

15.92

Date of collection & analysis:

Oven make and model:

Process lethality:

Operating parameters:

D-Reductions:

>10

Facilitator conducting analysis:

#### Process Data:

Time (s)	Cum. Temp. (°F)	F Value (min)	Log Reduction	Cum. Log Reductions
5	179.24	0.00	0.00	0.00
10	177.91	13.40	8.88	8.88
15	176.51	13.88	9.79	9.79
20	175.05	10.31	9.88	9.88
25	173.55	8.10	1.01	10.89
30	172.11	0.88	1.00	11.89
35	170.71	3.43	1.19	12.88
		0.00	0.00	12.88





## Validating the Kill Step

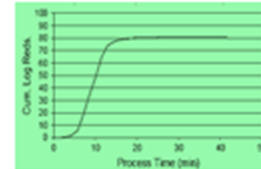
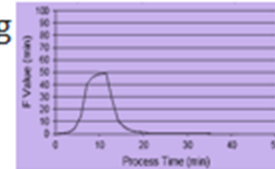
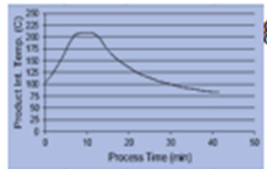
- D value is the time required at a certain temperature to reduce the bacterial load by “one log”
  - Tortillas: 4.57 secs
- Z value is the change in the temperature, in degrees Fahrenheit required to reduce the bacterial load by “one log”
  - Tortillas: 15.92

T-ref: Reference Temperature



## Output

- Automatically determines the total process lethality
- Generates three graphs:
  - Product internal temperature
  - $F$  - value/min



## The MOLE



## Baking Process Kill Step Calculator

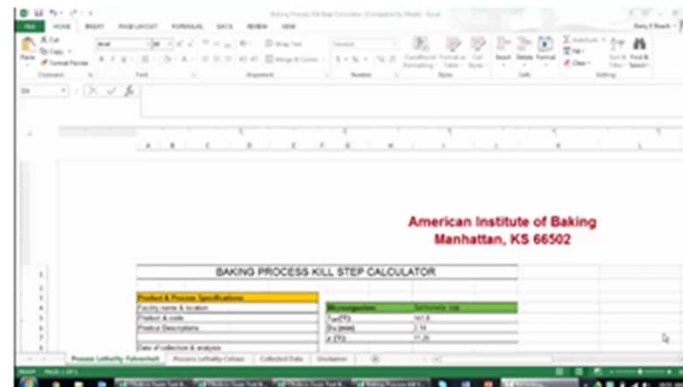
If the desired log reduction is achieved for the baking process, the process lethality report generated can be used as a supporting documentation for FSMA validation and verification process



## The MOLE



## The MOLE



## Baking Process Kill Step Calculator



## Baking Process Kill Step Calculator





## Baking Process Kill Step Calculators

- AIB released Baking Process Kill Step Calculators for:
  - Hamburger buns
  - Whole wheat pan bread
  - Cake muffins
  - Crisp cookies
  - Soft cookies
  - Cheesecakes
  - Doughnuts
  - Nut Muffins
  - Flour Tortillas
- Download the calculators free from AIB's website complete with instructions and procedures



## Benefits of Kill Step Validation Research

- Greater food safety assurance
- Protects consumers, builds confidence
- Demonstrates FSMA compliance
- Meeting regulatory agency standards
- Avoiding costly independent research



## AIB Can Help

### Public Seminars

- Foundations: Labeling of FDA Regulated Foods
- **FSMA: The Pathway to Compliance**
- FSPCA Foreign Supplier Verification Programs
- FSPCA Preventive Controls for Human Food
- FSPCA Preventive Controls for Human Food + HACCP Integration for FSMA Compliance with Kansas State University
- **HACCP Integration for FSMA Compliance**
- Specializations: Advanced Labeling of FDA Regulated Foods



## AIB Can Help

### Online Training

- Can You Handle It? Webinar Series
- FSMA Awareness Webinar Series
- HARPC Online
- HACCP Integration for FSMA Compliance
- Making the Transition to FDA's New Nutrition Facts Label Webinar

### Private Training

- Can't make a seminar? Most of our seminars are offered as private training, you choose the time and place.



## AIB Can Help

### Download the KSV calculators

- Go to [www.aibonline.org](http://www.aibonline.org)
  - Click on “Develop your Product Solutions”
  - Then click “Baking Process Kill Step Calculators”
- Whole wheat pan bread - [Read the procedures](#) | [Download now](#)
- Basic cake muffins - [Read the procedures](#) | [Download now](#)
- Cheesecake - [Read the procedures](#) | [Download now](#)
- Crispy Cookies - [Read the procedures](#) | [Download now](#)
- Doughnut - [Read the procedures](#) | [Download now](#)
- Flour Tortillas - [Read the procedures](#) | [Download now](#)
- Hamburger buns - [Read the procedures](#) | [Download now](#)
- Nut Muffin - [Read the procedures](#) | [Download now](#)
- Soft Cookies - [Read the procedures](#) | [Download now](#)
- See the tutorial if necessary



### Need More Help?

- Don't have a data-logging device? AIB's experts can use our thermal-logger to validate your baking process for you!
- Commercial bakeries looking for additional support can schedule Kill Step Validation Consulting where one of our professional team members will visit your bakery to identify the oven's cold spot, determine the product's internal temperature, and calculate the lethality of the baking process
- Schedule your Kill Step Validation Consulting by sending us an email or calling 1-800-633-5137



Questions?

