Kill-Step Validation for Food Safety

Kantha Channaiah, Ph.D.
Director of Microbiology
AIB International

Agenda

- Food safety
- What is validation?
- Why do we need to validate a kill step?
- FDA-FSMA requirement
- Validation road map
- Revalidation
- Verification
- Benefits of validation, and
- Q&A

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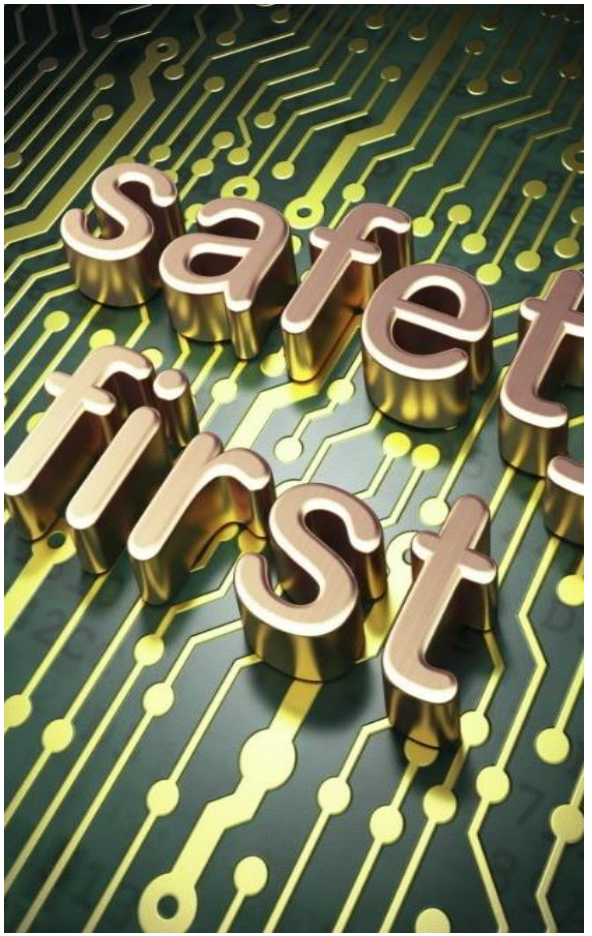
Pet Food Safety

- Who is responsible for food safety?
- Food safety is everyone's job
  - Reducing risks from foodborne pathogens is an essential part of every pet food manufacturer's responsibility to protect both its consumers and its business



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How Do Pathogens Get Into Our Facilities?

- **Raw materials**
  - Primary source of contamination
- **Breakdown in facility integrity**
  - Open doors
  - Broken windows
  - Roof leak
  - Wall crack
  - Air intake/compressed air
- **Breakdown in GMPs**
  - Employee hygiene
  - Facility sanitation
  - Post lethality sanitation practices
  - Employee traffic
  - Equipment traffic, etc.

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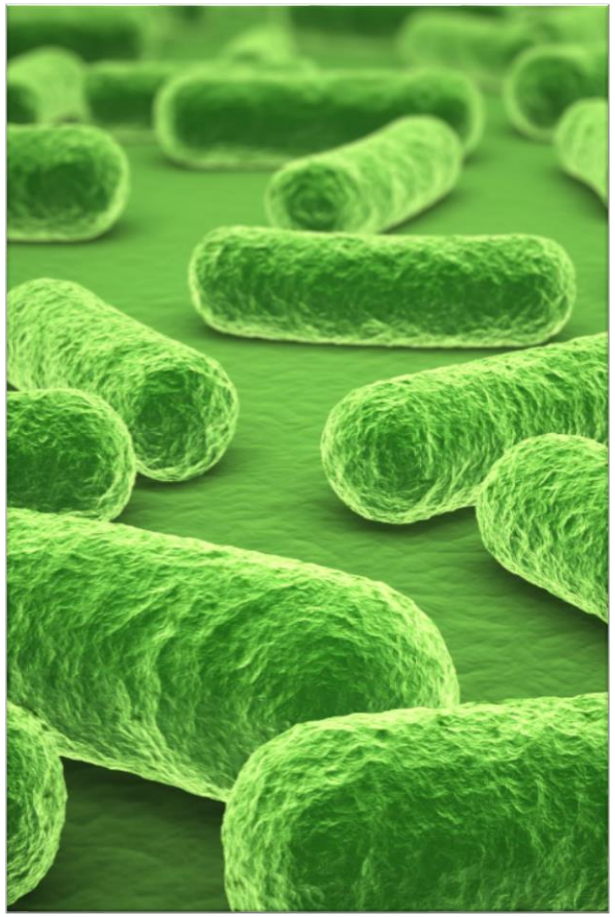
Why Do We Need to Control Microorganisms?

- Microorganism growth causes:
  - Odor
  - Alters appearance
  - Taste
  - Decay
  - Decreases shelf life
  - Affects overall product quality
  - Causes diseases, and
  - Deaths



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Pet Food: Outbreaks and Recalls

The FDA seeks to minimize Salmonella illness in pets
June 12, 2015

CDC

FDA now testing pet food, pet treats for Salmonella
November 2011

FDA seeks to minimize Salmonella illness in pets
June 12, 2015

Pro-Pet

ABC recalls pig ear chew pet treats for *Salmonella* contamination (
May 31, 2011)

dog, cat food on
contaminatio
February 7, 20

FDA

ABC recalls rabbit and Macaw diets a ossible Listeria monocytogenes
May 16, 2017

MNO Pet Foods expands recall of Chicken Soup dry dog food
(April 27, 2012)

XYZ pet food pay settlement in *Salmonella* cases (April 25, 2016)

BBB farm cooperative recalls cat food
(August 11, 2015)

PQR recalls select chicken pet foods due to *Salmonella*
July 24, 2015

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Preventive Controls / CCP

- Whether one calls it as a CCP or treatment it's the responsibility of the manufacturer to make the finished product safe
- Food manufacturers will need to provide scientific evidences/validation that their preventive control(s) is capable of controlling the identified hazard

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Why Do We Need to Validate a Kill Step?

- Although most pet food products undergo a supposed kill step at the point of production, there is often a lack of scientific proof
- FDA-FSMA requires **validation and verification** of a kill step (21 CFR 507.3)

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What is Validation?

A scientific evaluation providing documentary evidence that a particular process is capable of consistently delivering a product, meeting its pre-determined performance standards

Validation: What Does FDA-FSMA Say?

- You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system (21 CFR 507.47)
- Can the food safety plan control the identified hazards?
- Must be performed (or overseen) by the PCQI

The Three Key FSMA Requirements:

1. Validation of preventive controls (prior to the implementation of food safety plan OR 90 days after the first production begins)
2. Provide scientific evidence, and
3. Keep documents/records accessible for FDA inspection

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Kill Step Validation: Requirements

- A successful validation study requires diverse expertise
  - Detailed design
  - Experienced microbiologist
  - Statistician
  - Containment facility (e.g., BSL 2 lab), and
  - A keen eye for sources of process variability

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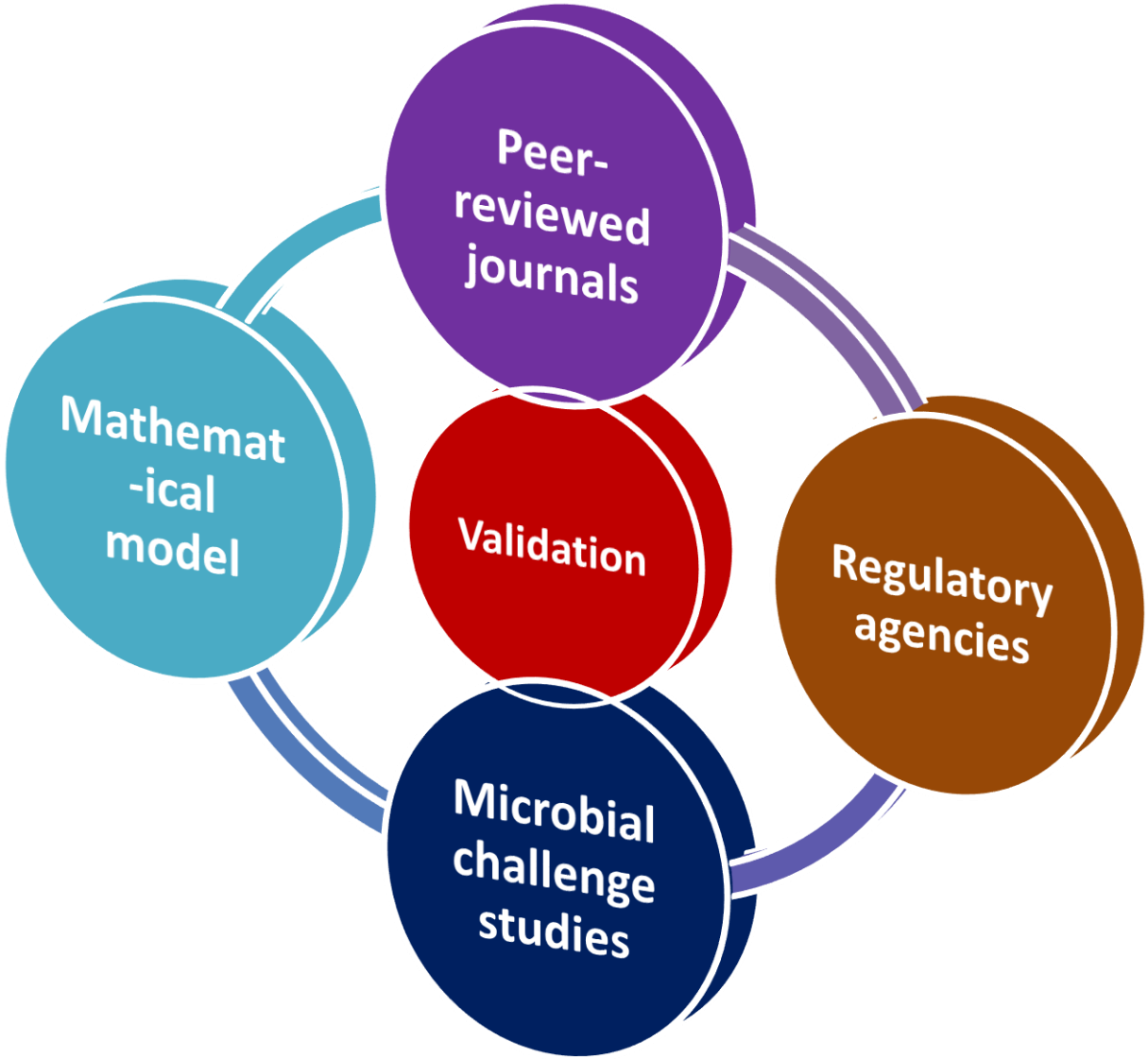
Ways to Prove Validation



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Kill Step Validation – Road Map

- Determine worst case scenario
- Choose a microorganism
- Maintain at least 6-7 log/g
- Conduct experiment
- Data analysis
- KSV report

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Kill Step Validation – Road Map

- Validate for the worst case scenario
- Examples:
  - Lowest cooking temperature
  - Fastest belt speed
  - Lowest zone temperature
  - Coldest spot possible
  - Shortest time exposed
  - Maximum load per batch
  - Lowest moisture content
  - Highest fat content, etc.

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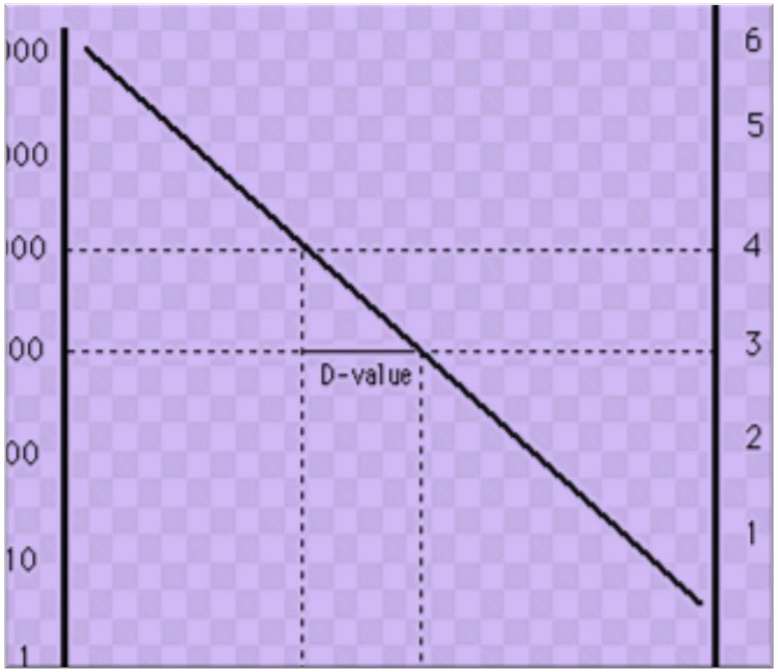
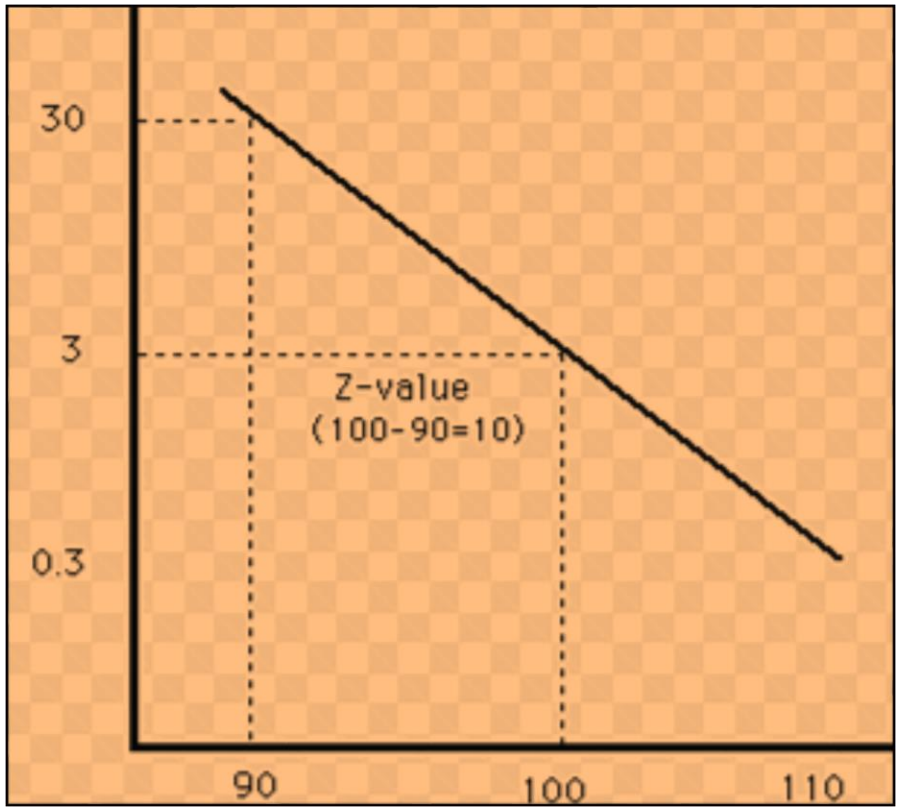
Microbial Kinetics

Decimal (D) value is the time required at a certain temperature to kill 90% of specific bacterial population or reduce the bacterial load by one log under specified conditions



Microbial Kinetics

Z value is the change in the temperature, in degrees Fahrenheit (°F) or Celsius (°C), required to reduce the specific bacterial load by a factor of 10 or by one log



Microbial Kinetics

Thermal Death Time (TDT) is the shortest time needed to kill all bacteria or microorganisms in a product at a specific temperature and under defined conditions

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Advantages of Microbial Kinetics

- Help determine the shortest time/ treatment, as well as proper treatment options
- D and *Z* values will allow us to adjust the time and temperature, thus optimizing the process

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Selection of a Surrogate or Pathogenic Bacterium

- Select the right surrogate or bacterial pathogen
- A surrogate of equal or greater resistance compared to the pathogen of concern

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Validation Report

- The validation report should include sections such as:
  - Introduction
  - Contact information
  - Background information
  - General information of the product
  - Parameters studied
  - Details of equipment (type & make) used
  - Validation methodology
  - TDT, Z-value, D-value (Optional)
  - Microbial strains used in this study
  - Results
  - Date of experiment
  - Detailed discussion
  - Conclusion and significance

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Revalidation

- Reanalysis of the food safety plan must take place
  - At least every 3 years

    and/or
  - For any significant change in the process parameters

You Do Not Need to Validate:

1. Sanitation controls in § 507.34(c)(2)
2. Recall plan, and
3. Supply chain program in subpart E

Who is covered under FSMA validation rule?

- All the FDA registered facilities
- Also, one need to complete within 90 calendar days after production of the applicable pet food first begins

FDA FSMA compliance deadlines

Business size	Subpart B CGMP	Subpart C HARPC
All others	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 18, 2017	Sept. 17, 2018
Very small Businesses (< $ 2.5 million/ year)	Sept. 17, 2018	Sept. 17, 2019

Verification

- The Application of methods, procedures, test and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to the establish the validity of the food safety plan (21 CFR 507.3)
- Are the preventive controls actually being properly implemented in a way to control the hazard?

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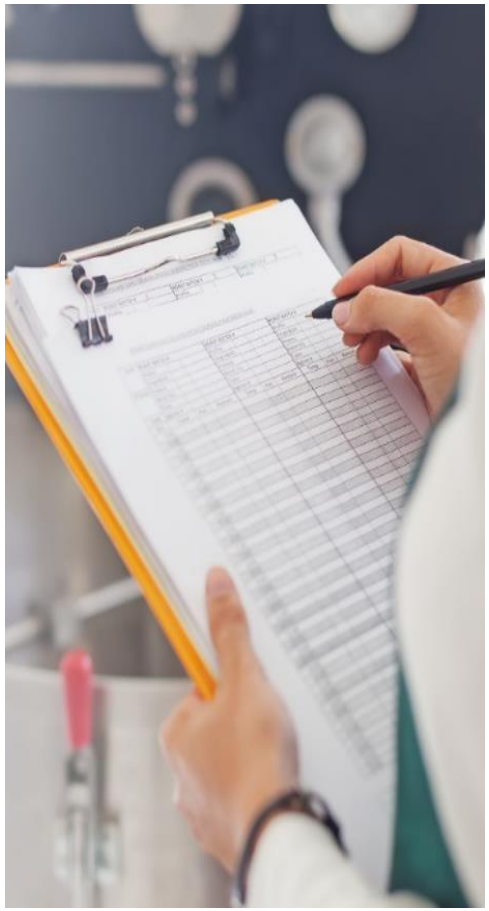
Benefits of Process Validation

- Assure maximum food safety and protect consumers
- Comply with FDA-FSMA standards
- Determine the effective treatment
- Save industry millions of dollars by avoiding recalls and other legal penalties due to outbreaks
- Retain customer's confidence, and
- Support business success



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Validation: Final Note

- In-plant validation using surrogates:
  Can have adverse sanitary or regulatory implication, should they survive!
- The **SUCCESS** of any validation study depends on:
  - HACCP plan
  - GMPs
  - Sanitation program
  - Pest control program
  - Good hygiene post-process handling procedures
- It is important to conduct process validation after ensuring these controls are established in a facility

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Questions

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