Kill-Step Validation for Food Safety

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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
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
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.
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
Pet Food: Outbreaks and Recalls

- PQR recalls select chicken pet foods due to *Salmonella* (July 24, 2015)
- BBB farm cooperative recalls cat food (August 11, 2015)
- ABC recalls rabbit and Macaw diets due to possible *Listeria monocytogenes* (May 16, 2017)
- MNO Pet Foods expands recall of Chicken Soup dry dog food (April 27, 2016)
- XYZ pet food pay settlement in *Salmonella* cases (April 25, 2016)
- The FDA seeks to minimize *Salmonella* illness in pets (June 12, 2015)
- FDA now testing pet food, pet treats for *Salmonella* (November 2011)
- ABC recalls pig ear chew pet treats for *Salmonella* contamination (May 31, 2011)
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
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)
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
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
Ways to Prove Validation

- Peer-reviewed journals
- Mathematical model
- Validation
- Regulatory agencies
- Microbial challenge studies
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
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.
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.
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
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
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
Revalidation

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

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<th>Subpart C HARPC</th>
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<td>Sept. 17, 2018</td>
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<tr>
<td>Very small Businesses (&lt; $ 2.5 million/ year)</td>
<td>Sept. 17, 2018</td>
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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 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?
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
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
Questions