Validation of Key Control Technologies/Processes in the Modern Production Environment

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PETFOOD R&D SHOWCASE 2018

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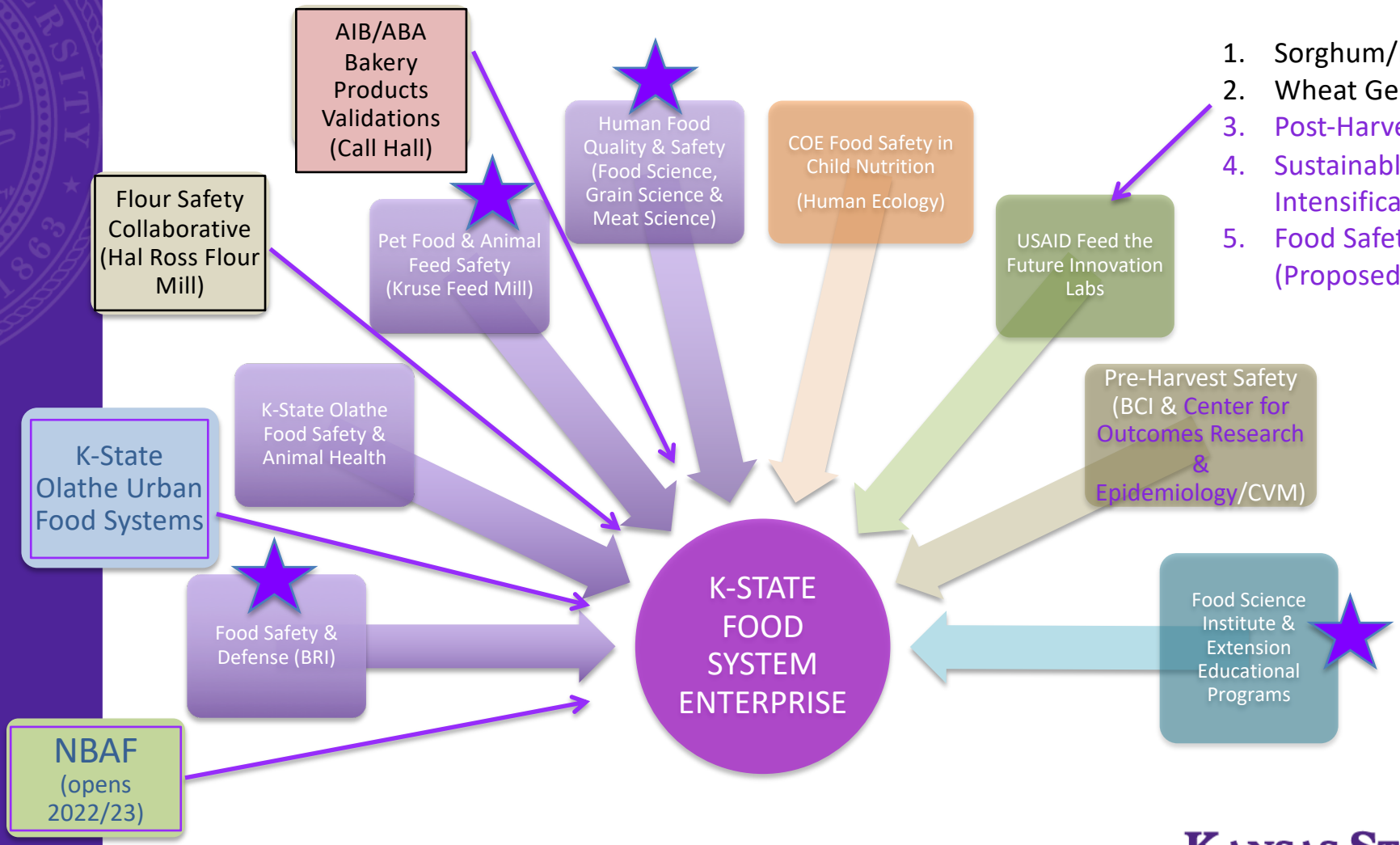
Welcome to the K-State Global Food System Enterprise



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Validation of Key Control Technologies/Processes in the Modern Food Production Environment

Plan for my talk (it's great to have a plan!):

- Generally define important aspects of **validation** in the context of using a food safety control system to produce safe consumer food products
- Talk about validation research that I've been involved in, providing specific examples of scientifically approaching validation studies
- A few "lessons learned" over the last quarter century

My team (those who do the heavy lifting!):

- K-State Food Safety & Defense Lab (FSDL)
- K-State-Olathe Food Microbiology
- K-State Feed Safety Research Lab (FSRC)
- K-State Diagnostic Medicine and Pathobiology Department
- Department of Grain Science
- Food Science Institute
- Biosecurity Research Institute
- AIB Food Safety Group
- Academic Collaborators
- **INDUSTRY COLLABORATORS**

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My team :

Why Bother with Pet Food Safety?

Annual US Human Foodborne Disease Estimates

- Estimated to cause **47.8 M illnesses**
- 3000 deaths
- 2-3% of foodborne illness cases may cause permanent health damage, which may never be traced back to the disease source 0

Pet Food Considerations

1) Pet gets sick from contaminated pet food/treats
2) Pet becomes asymptomatic carrier of human disease agents
3) Carrier pets contaminate human environments/contact
4) People handle pet foods/treats
5) Opened pet food by consumer allows pathogen outgrowth
6) Humans eat pet foods
7) Brand image and regulatory compliance

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Sickly Pet Food Recalls 2018 (n=23)

- *Salmonella*
- *Listeria*
- *Clostridium botulinum*
- *E. coli*
- Hormones/Chemicals
- Raw or Raw Frozen
- Freeze dried
- Kibbles

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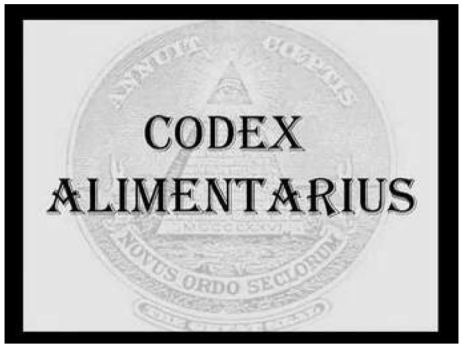
Important Concerns

- Trend to organic or natural foods (and “raw” foods)
- Antibiotic resistant bacteria
- New packaging & processing techniques
  - Minimal processing, non-thermal interventions
- Longer shelf life of many products
- Food and ingredients imported into the US from countries with less food safety oversight
- Possible use of food as a vehicle for terrorism
- Molecular detection/characterization techniques, WGS, attribution

BOTTOM LINE

From the Codex Alimentarius

- Food producers, processors and preparers must control relevant hazards potentially associated with foods at all points
- Using systems-based food safety controls (flexibility afforded to selection of the controls)
- By conducting validation to demonstrate that these selected controls are consistently capable of achieving the intended level of hazard control.



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FSMA Preventive Controls:

- Process Controls
- Sanitation Controls
- Other Controls

- ✓ **Verification:** Activities to determine whether a preventive control is operating as intended and to establish the validity of the food safety plan.

- ✓ Scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard is an example of a verification activity.

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Validation and Prevention of Multi-Syllable Germs in Manufactured Foods…

VALIDATION

- Specific technology
- Specific processing schedule
- Whole food safety plan
- Verify and re-validate

- Training
- Personnel Hygiene
- Ingredient Specs
- Environmental Control
- Background Checks
- Cold Chain Management

PREVENTION

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Prevent / Prevention

Merriam-Webster:

① to keep something from happening

② to stop someone from doing something

③ to be in readiness for

Pre-Requisite Programs
HACCP
FSMA
Risk Assessments

Validate / Validation

Merriam-Webster:

① to make legally valid

② to grant official sanction to

③ to confirm the validity of

④ to support or corroborate on a sound or authoritative basis

- experiments designed to validate the hypothesis

Verify / Verification

Merriam-Webster:

① to confirm or substantiate

② to establish the truth, accuracy, or reality of

- "verify the claim"

Monitoring: collection of information (preferred real-time and continuous) to establish that the control measure is functioning within limits.

Verification: on-going determination that control measures have been implemented as intended (observation of monitoring activities and review of records).

Prevent, Validate, Monitor & Verify Your Food Safety System

You process RTE kibbled cat food. To ***prevent*** your product from making cats and people sick, you apply a ***validated*** high intensity pre-conditioning processing ***technology*** (HIP) as your product's primary food safety control measure. You expect HIP to render a final packaged food with no pathogens.

You continually ***monitor*** your food safety control measure by recording processing time and temperature of each lot/batch processed to ensure your HIP process reaches ***critical limits*** set during inoculated validation studies conducted at the KSU FSRC.

Your supervisor ***verifies*** that all control measures during your shift were actually recorded properly by reviewing production logs and confirms that implementation of control measures were according to design.

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Approaches to Validation (Codex)

① Scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure.

② Valid experimental data that demonstrate the adequacy of the control measure.

③ Collection of data (with statistical power) during operating conditions in the whole food operation.

④ Mathematical modeling.

⑤ Surveys.

PEER-REVIEWED ARTICLE

Food Protection Trends, Vol 33, No. 2, p. 95–104

6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

Validation of Antimicrobial Interventions for Small and Very Small Processors:

A How-to Guide to Develop and Conduct Validations

CONSORTIUM OF FOOD PROCESS VALIDATION EXPERTS (CFPVE)[1]*

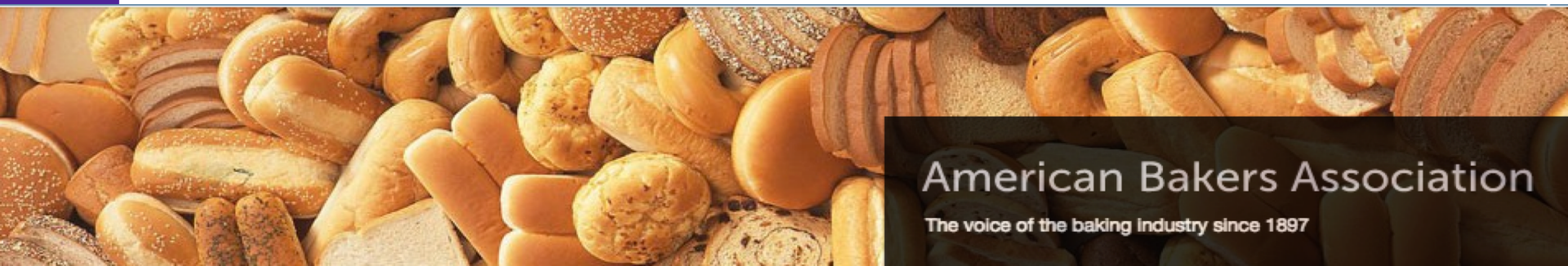
[1]The CFPVE consists of representatives from Auburn University, Colorado State University, Iowa State University, Kansas State University, Oklahoma State University, Pennsylvania State University, Texas A&M University, Texas Tech University, the United States Department of Agriculture — Agricultural Research Service, the University of Arkansas, the University of Nebraska, and the University of Wisconsin.

Validation of Bakery Products Manufacturing Processes

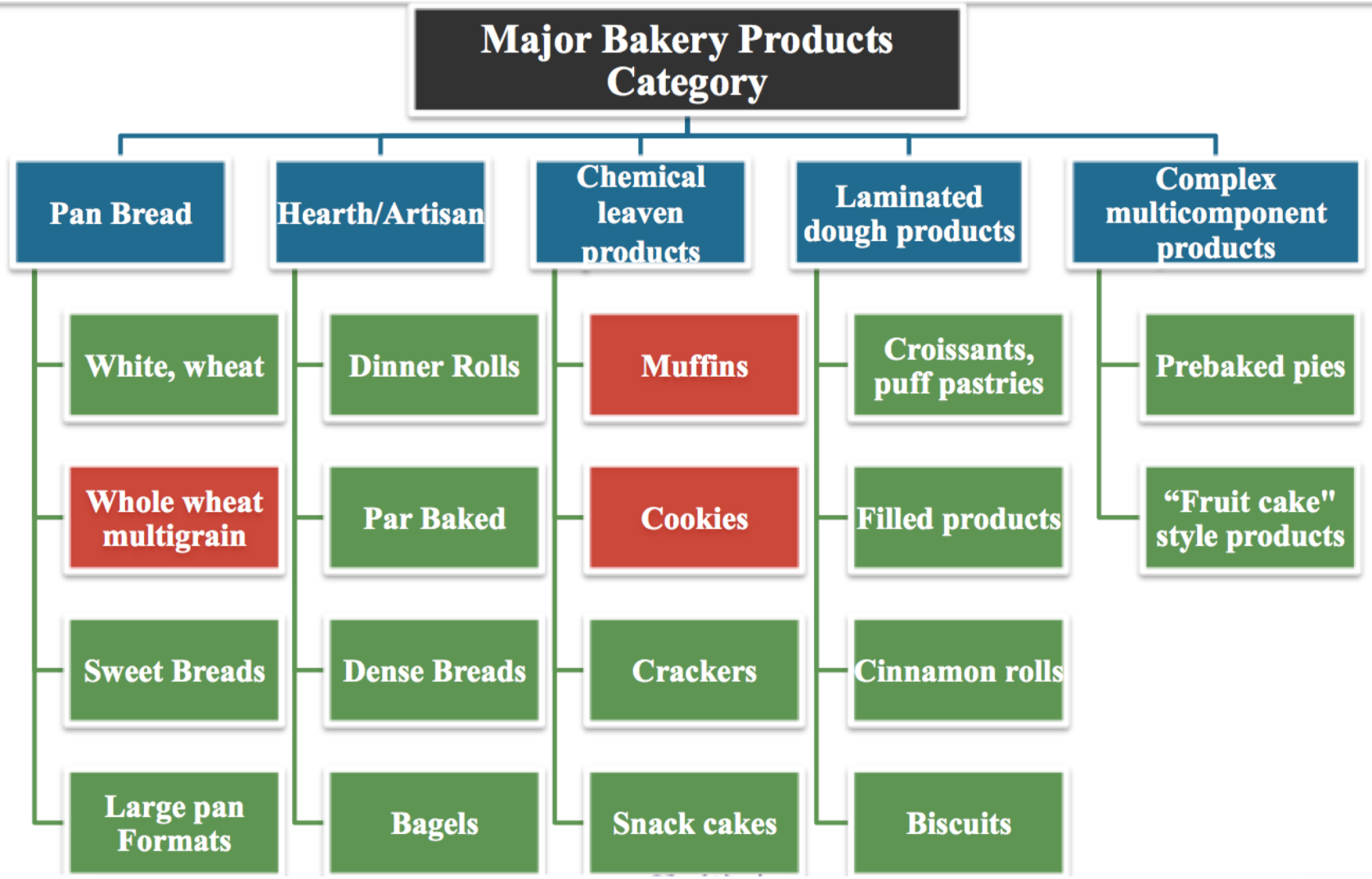
- AIB International / American Bakers Assoc.
  - Represents >1000 baking facilities and their suppliers
- **The need:** Baking industry required to comply with FSMA to implement "Preventive Controls" for hazards reasonably likely to occur in all products.
- **The issues:**
  - Sparse published information to use for validation purposes
  - Huge and diverse bakery product portfolio
  - Many small companies with limited resources
  - Why should individual bakers try to validate all of their processes when AIB/ABA can provide the information for broad commercial use and implementation?

Validation of Bakery Products Manufacturing Processes

- **The Approach:**
  - AIB teamed up with FSDL to envision approach to best assist bakery industry
    1. What are bakery product categories and what product types fall into these categories?
    2. What product types have the most sales volume?
    3. What product types have the potentially highest pathogen risks?
    4. What pathogens are reasonably likely to occur in each product?
    5. What product(s) should be validated first based on above (and ease of setting up lab and perfecting procedures…FSMA pressure!)?



Next generation validation research: Phase I



Baking validation next generation research:
Criteria and justification

Whole grain wheat bread

- Size (1lb loaf)
- High moisture
- High water activity (a_w)

Muffins

- Chemically leavened
- High sugar
- High moisture
- High fat

Cookies

- Chemically leavened
- Multi-component
- Low moisture
- Low water activity (a_w)

Validation of Bakery Products Manufacturing Processes

- **The Approach:**
  - Decided that first pathogen-inoculated study would be conducted by FSDL on hamburger bun manufacturing process against *Salmonella*
  - ABA felt need to simultaneously validate non-pathogenic surrogate (*Enterococcus faecium*) for possible in-plant studies later

① Which *Salmonella* strains? What about *E. faecium*?
② How to inoculate? … flour, dough
③ How to prepare and administer the inoculum?
④ What inoculation level to target, and why?
⑤ What *Salmonella* and *E. faecium* culture methods to use?
⑥ What kind of data did we need and what experimental design would give it to us?

Validation of Bakery Products Manufacturing Processes

- **The Approach:**
  - Experimental Design

① Inoculate flour using stationary phase cultures to ca. 10^6 cfu/g
  - *E. faecium* ATCC 8459 (NRRL B-2354)
  - *Salmonella* Typhimurium, Newport, and Senftenberg
    Dry flour to original weight and store 48 h

② Prepare dough according to commercial protocol
  - Formula, mixing, proofing (AIB oversight)

③ Baked to mimic industrial process relative to internal temp profile?
  - AIB collected abundance of commercial oven data for hamburger buns
  - AIB process experts ensured that lab oven settings yielded proper quality and approximated commercial ovens

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Validation of Bakery Products Manufacturing Processes

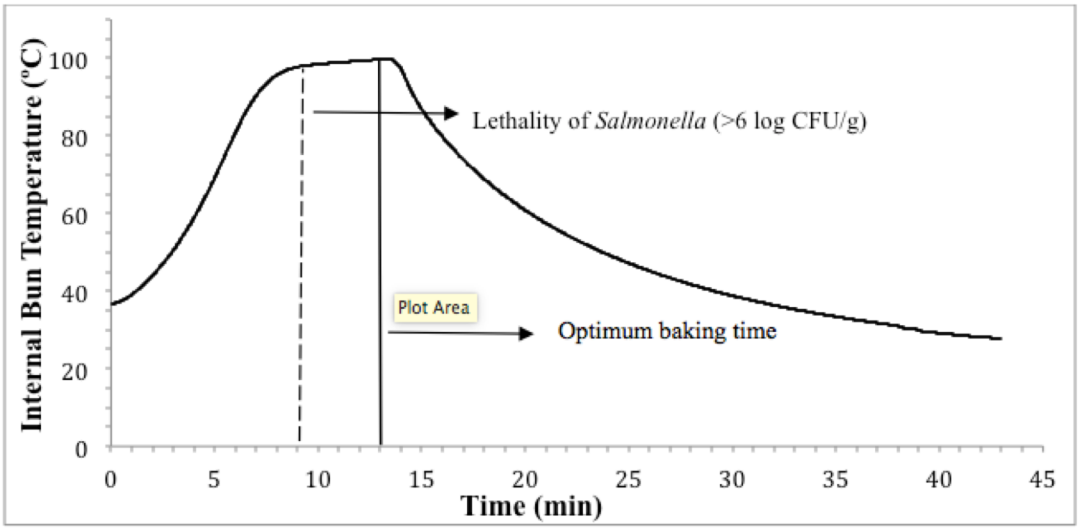
- **The Approach:**
  - Hamburger Bun Baking Experiments

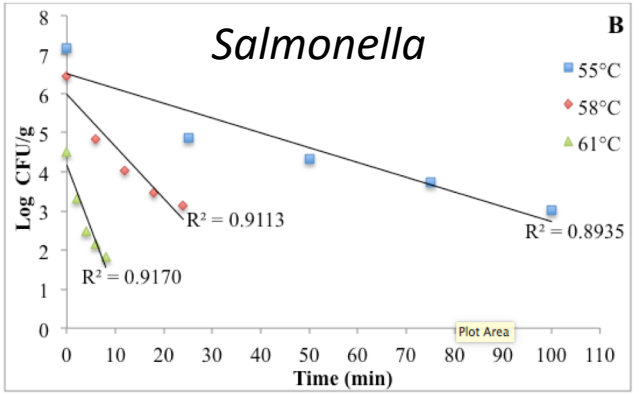
① Conducted *Salmonella* survival during baking trials

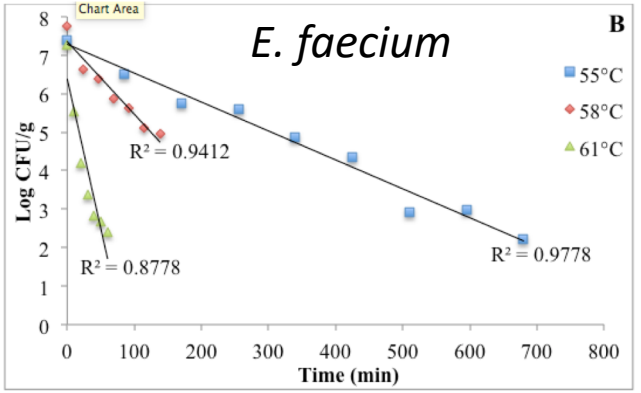
① Conducted *E. faecium* surrogate studies to compare to *Salmonella* outcomes.

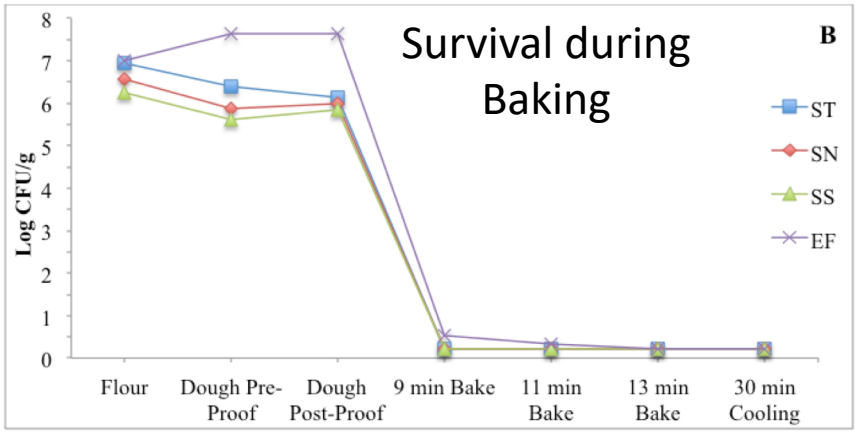
② For each *Salmonella* serotype, the *Salmonella* cocktail, and *E. faecium*…generated D-values and z-values during heating of inoculated dough in temperature controlled waterbaths.

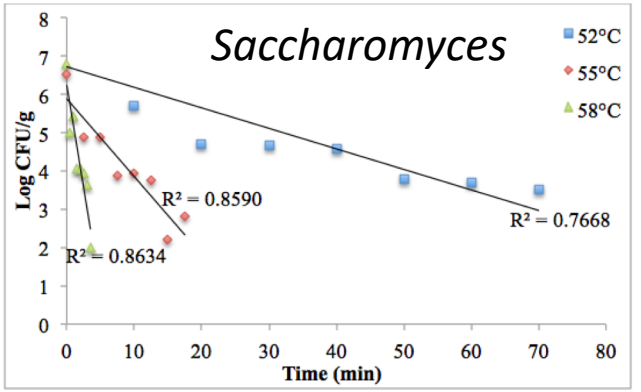
Validation of Bakery Products Manufacturing Processes











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Microbial kinetics study

Table 1. D-values (min) and z-values (°C) of a 3-strain *Salmonella* spp. cocktail, and *Enterococcus faecium* ATCC 8459 in hamburger bun dough

	***Salmonella* spp.**		***E. faecium***	
	BHI/XLD[a]	**XLD[b]**	**BHI/mEA[c]**	**mEA[d]**
Temperature (°C)				
55	28.64 ± 5.19	21.30 ± 2.61	133.33 ± 0	87.21 ± 4.74
58	7.61 ± 0.61	7.53 ± 0.61	55.67 ± 9.0	45.33 ± 6.79
61	3.14 ± 0.32	2.29 ± 0.21	14.72 ± 4.11	6.14 ± 0.47
z-value	6.68 ± 0.94	6.22 ± 0.32	6.25 ± 0.80	5.20 ± 0.05

Validation of Bakery Products Manufacturing Processes

- **The "Take-Home" from Hamburger Bun Trials:**

① Typical HB oven baking process (425°F) will eliminate >6 logs of *Salmonella* originating in contaminated flour well before fully-baked quality standards are reached.

② *Saccharomyces cerevisiae* **is not** an acceptable surrogate for in-plant thermal inactivation studies.

③ *E. faecium* had higher D-values than *Salmonella*…can be used as a non-pathogenic surrogate in in-plant studies, but would over-estimate thermal lethality relative to *Salmonella.*

④ D- and z-values from these studies used to predict lethality of other commercial HB manufacturers.

⑤ FDA very happy! (AT LEAST THEY'RE GETTING THERE)

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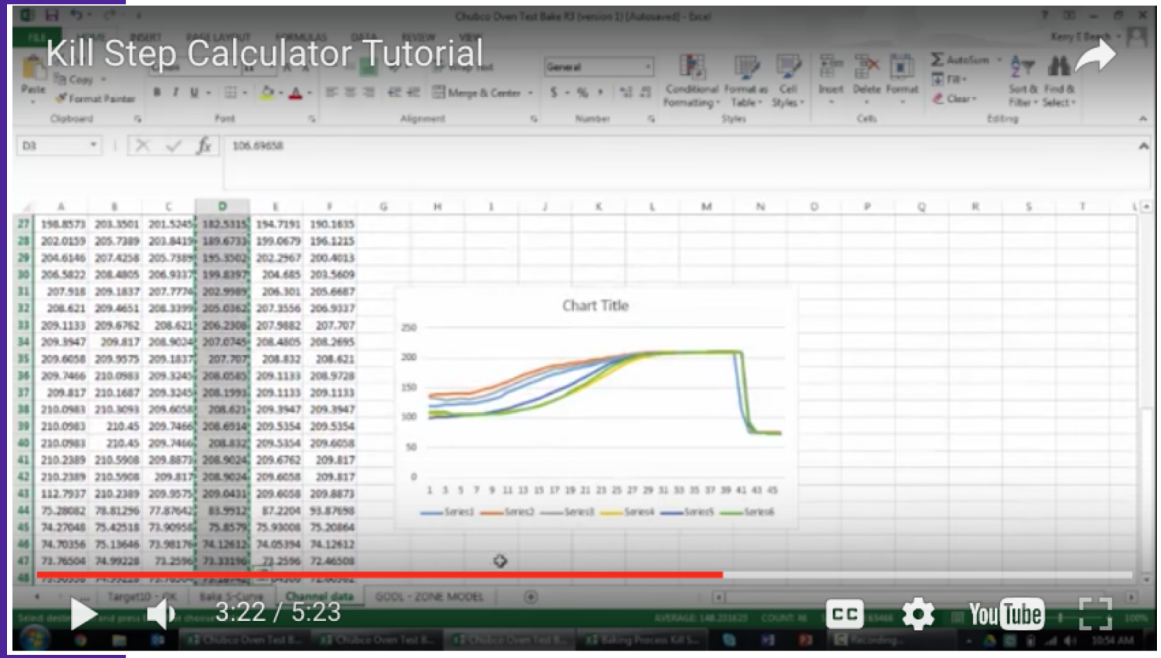
Baking Process Kill Step Calculators

Empowering bakeries to validate their food safety preventive controls



Our Partners

American Bakers Association

The University of Georgia

Kansas State University

Validation of Bakery Products Manufacturing Processes

fcpaprofessor.com

- **Lessons Learned:**
  1. Put in as much effort as necessary into preliminary trials to ensure the accuracy and applicability of your study results.
  2. Take advantage of industry experience and insight in designing and interpreting your studies, but stand strong if necessary.
  3. Regulatory agencies can be valuable advisors to your research (don't be afraid of them).
  4. Journal reviewers can be a pain in the ***, but in the end they can make you think a little harder and can help you improve your research program.
  5. Even within "bakery products" category, huge differences in process lethality exist…don't speculate on food safety.

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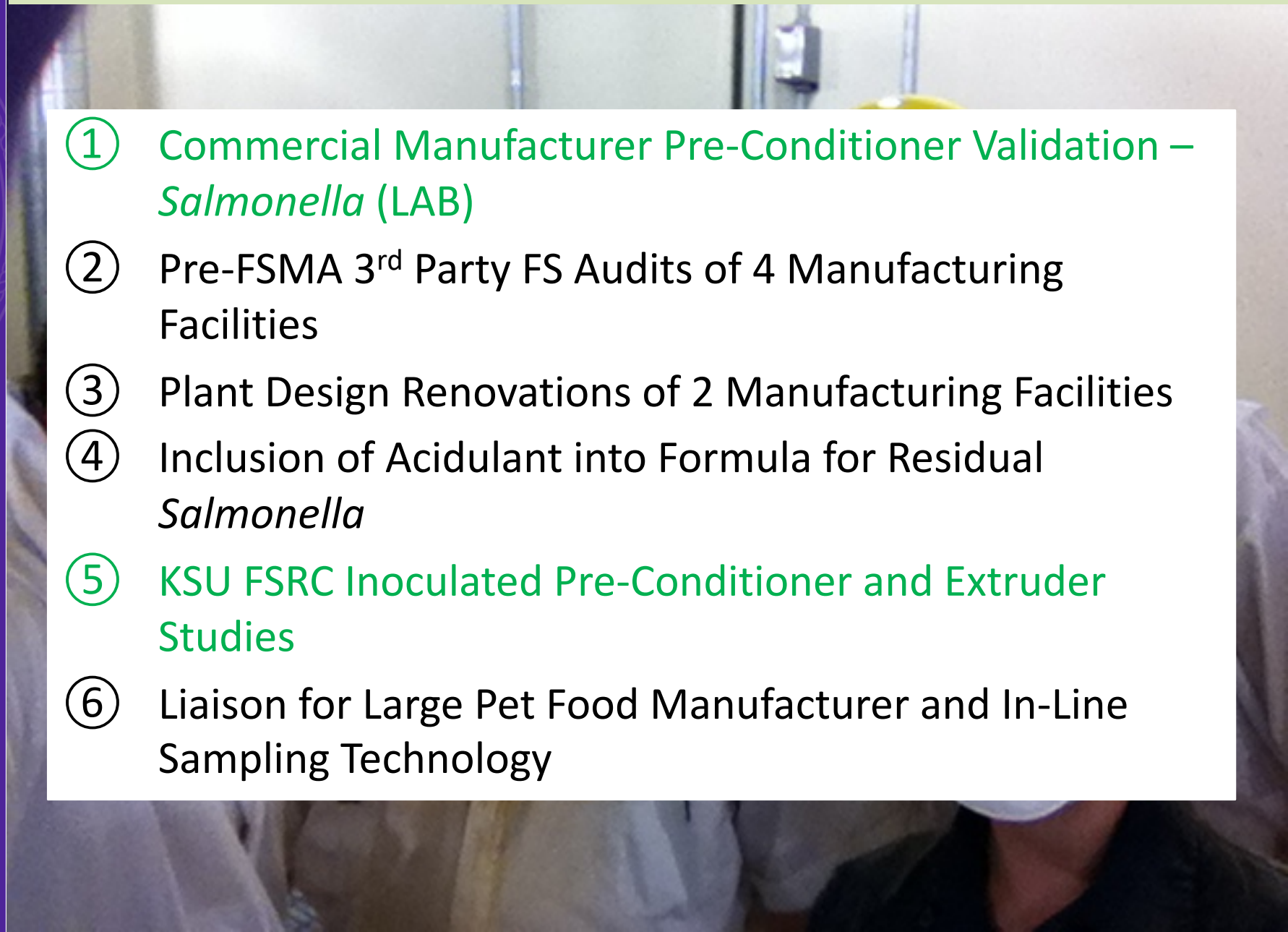
KSU Kibble-Style Pet Food Safety Activities



① Commercial Manufacturer Pre-Conditioner Validation – *Salmonella* (LAB)

② Pre-FSMA 3rd Party FS Audits of 4 Manufacturing Facilities

③ Plant Design Renovations of 2 Manufacturing Facilities

④ Inclusion of Acidulant into Formula for Residual *Salmonella*

⑤ KSU FSRC Inoculated Pre-Conditioner and Extruder Studies

⑥ Liaison for Large Pet Food Manufacturer and In-Line Sampling Technology

Efficacy of a High-Intensity-Preconditioner for Reducing *Enterococcus faecium* Populations (as a Non-Pathogenic *Salmonella* Surrogate) in Kibble-Style Pet Food

O.H. Kruse Feed Technology
Innovation Center
Manhattan, KS

Kansas State University
GRAIN SCIENCE & INDUSTRY

fsi

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E. faecium as a Surrogate

- ATCC 8459 (NRRL B-2354)
- Approved for use in U.S. manufacturing facilities (BSL-1)
- Historically, has been used as a surrogate for *Salmonella* spp. in thermal processing
  - Thermal processing of almonds (ABC, 2014; Jeong et al., 2011)
  - Suitable to validate extrusion processes (Bianchini, 2014)
  - Hamburger bun processing (Channaiah, 2016)

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Objective

Validate three operational set-ups for a high-intensity-preconditioner (HIP) to control *Enterococcus faecium,* as a non-pathogenic surrogate for *Salmonella*, in kibble-style dog food formulation.

Wenger ® HIP System

- Mix, hydrate, and pre-cook product
- Two independently driven shafts
  - speed and rotational direction
- Greater capacity
- Greater mixing intensities
- Greater product retention time range

Experimental Design

- 3 treatments (trt)
- 2 replications (rep)
- Inoculated 500 lbs dry dog food mix
- 6 log cfu/g of *E. faecium* (15 min attachment period)
- Fed into HIP hopper (450 kg/h rate)
- Run 10 min to establish steady-state HIP conditions at each trt parameter
- Collected triplicate samples in chilled buffer to analyze
- Recovered surviving *E. faecium* (2 agars) to quantify log reductions

Trt	Shaft speed (big-small RPM)	Temp. (°C)	Resonance time (sec)	Shaft direction (big-small)
1 (slow, low temp)	200-200	68 ± 2	154	
2 (fast, low temp)	300-300	68 ± 2	65	
3 (fast, high temp)	300-300	90 ± 1	65	

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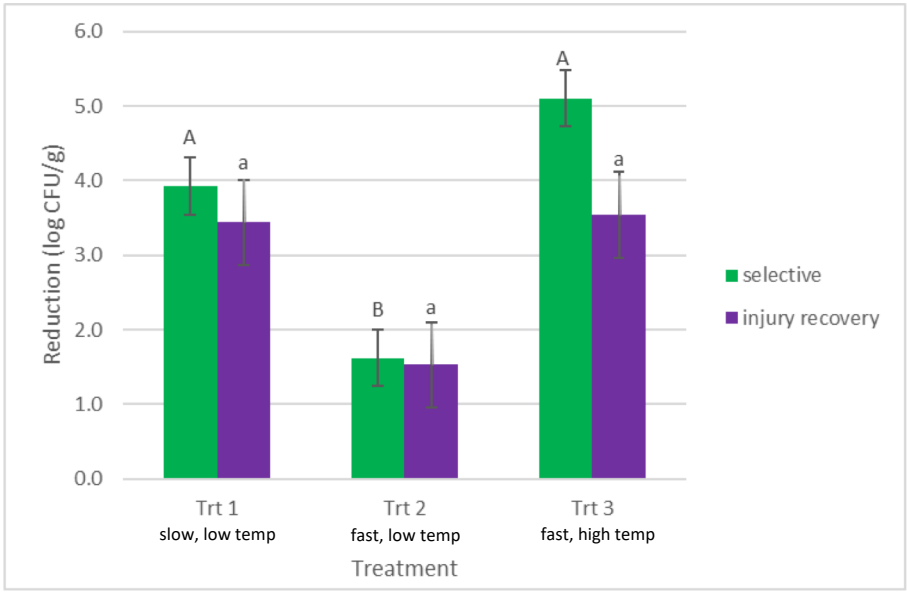
Results

Selective media:

- Trt 2 (fast, low temp) was significantly ($P > 0.05$) less effective at reducing *E. faecium*

Injury recovery media:

- All treatments resulted in lower reductions
- Sub-lethally injured cells



^{A,B} indicates treatment differences that differ statistically ($P \leq 0.05$) across selective media reductions
^{a,b} indicates treatment difference that differ statistically ($P \leq 0.05$) across injury recovery media reductions

All treatments resulted in adequate reductions (1.5-3.5 log CFU/g) for a "pre-cook" step in kibble-style pet food processing

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Significance

- Validated three HIP processes for reducing *E. faecium*
  - Indicative of the lethality effect expected for *Salmonella* spp. (Quite conservative estimate)
- Pet food processors can use this information to help define critical control points when using an HIP system

Tiya Zhou

Masters Thesis (2016)

Residence Time and Survival Studies for *Enterococcus faecium* as Surrogate for *Salmonella* During Preconditioning and Extrusion Processing of Dry Expanded Pet Food

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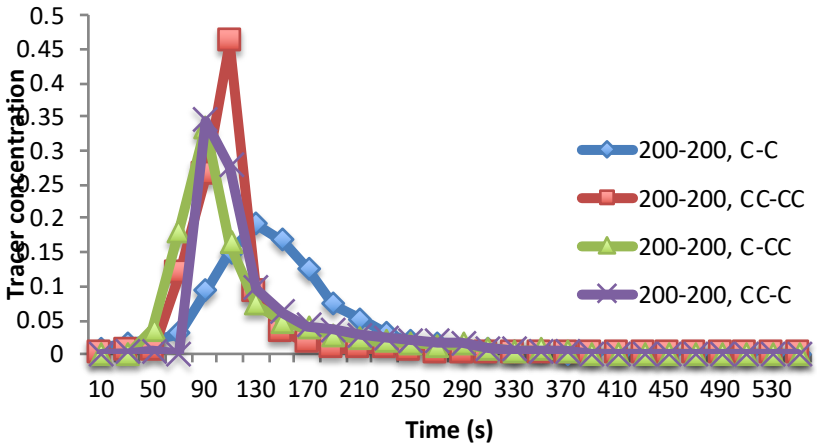
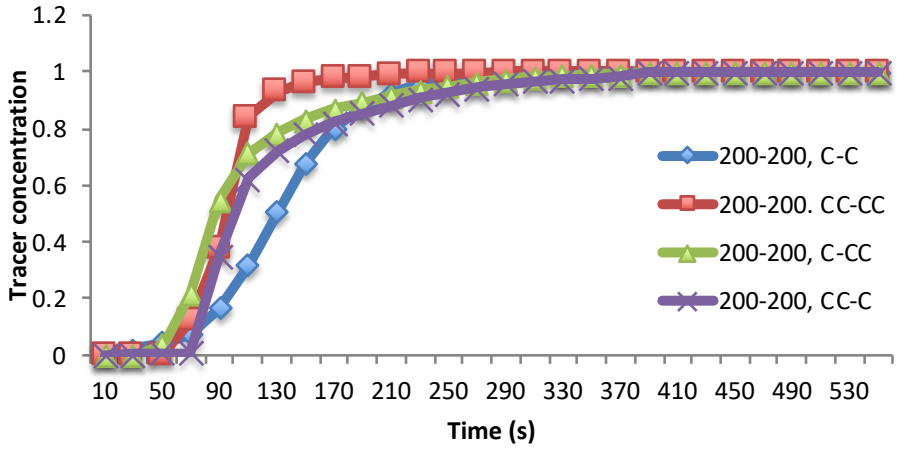
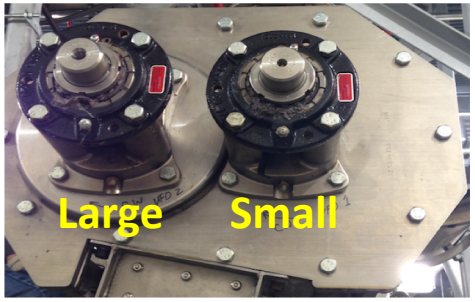
Effect of shaft direction on RTD & uniformity

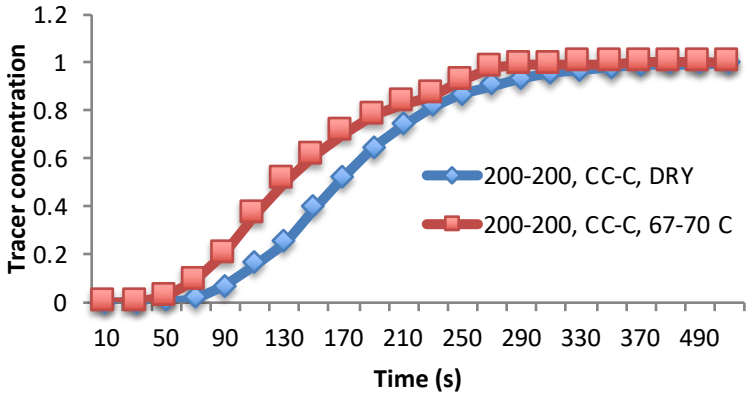


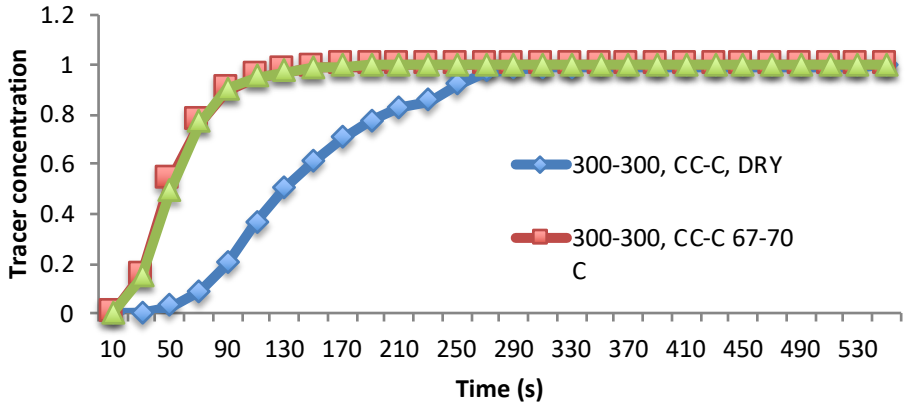


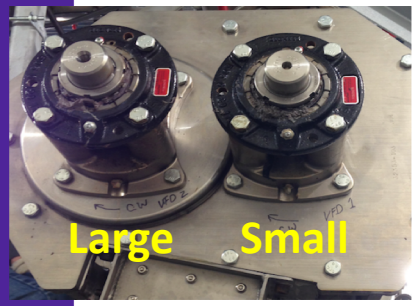


	Residence time	Uniformity
200-200, C-C	144 s	99
200-200, CC-CC	106 s	41
200-200, C-CC	116 s	99
200-200, CC-C	129 s	119

Effect of steam addition on RTD & uniformity



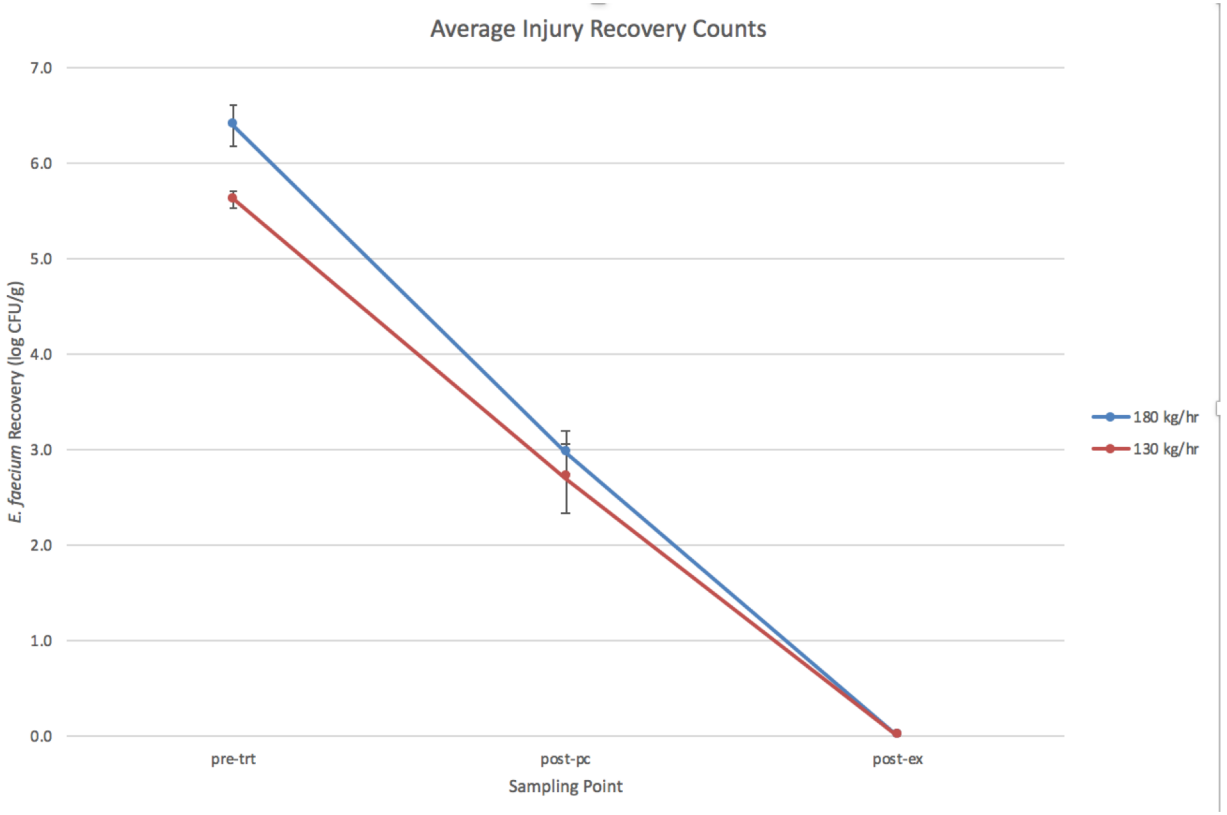




Treatments			Residence time	Uniformity
Shaft speed	Shaft direction	Steam addition & temp		
200-200	↻↺	0%, room temp	177s	151
200-200	↻↺	7%, 67-70 °C	155s	142
300-300	↻↺	0%, room temp	152s	144
300-300	↻↺	7%, 67-70 °C	65s	53
300-300	↻↺	9%, 89-91 °C	66s	53

Did we kill any *E. faecium*?

Did we validate the kibble manufacturing process for control of *Salmonella*?



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Conclusion

- Extruder successfully removed *E.faecium*
- High shear contributed
- Low IBM → low thermal energy input
  - Poorer expansion
  - Worse inactivation

DOES THIS TAKE CARE OF EVERYTHING FOR YOUR FOOD SAFETY PLAN FOR THIS PARTICULAR PRODUCT ?

THANK YOU !

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