MICROBIAL CHALLENGE STUDIES: PUTTING THE PIECES TOGETHER

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CHALLENGE STUDIES: PUTTING THE PIECES TOGETHER

- Brendan A. Niemira – When, why, and how to do challenge studies
- Alvin Lee – Surrogates and proper strain selection
- Eric Moorman – Case studies of HCAI and other viruses
- Q & A

THE CHALLENGE OF CHALLENGE STUDIES

- Microbial challenge studies are used to simulate contamination events
  - Introduction of contaminants
  - Failures of process controls
  - Out-of-spec operations in handling, distribution, preparation
- Control the problem in simulation, control the problem IRL
- Theory vs. practice
- Lots of ways to design bad/wasteful/misleading challenge studies

THE CHALLENGE OF CHALLENGE STUDIES

A bad challenge study will give you useless results, wasting time and money.

A REALLY bad challenge study will give you *misleading* results, not only wasting time and money, but leading you to implement processes and controls that aren't proper controls at all.

WHEN TO RUN A CHALLENGE STUDY

- Microbial contamination is a) happening, or b) is an identified risk
- Processes, formulations, ingredients have changed
- New customer requirements
- New regulatory standards
- Novel or unfamiliar organisms of concern become present
  - More on this later from Dr. Moorman
- Emerging research sheds light on old mysteries

WHEN TO RUN A CHALLENGE STUDY

- Challenge study will quantify the response of a particular organism to a particular set of processes on a particular commodity/test bed
- If you only have data for a process that is sort of like yours…
- … for a product that is kinda like yours…
- … for an organism / species/ strain that is somewhat related …
- … under storage conditions not really like yours…
- … it might be time for a challenge study.

WHY RUN A CHALLENGE STUDY

- Lots of useful data exists for microbial responses
  - May not be sufficiently applicable
  - Extrapolation from existing models result in out-of-spec operations
- New formulations / products / standards / organisms of concern can demand new process validation
- Represents an investment of time, money, credibility
- Outcomes: safer product, more reliable processes, no 3:00 am phone calls

HOW TO RUN A CHALLENGE STUDY

- Take the time to define your problem
  - What question are you trying to answer?
  - How does that translate to a proper challenge study?
- Product formulation has changed
  - "I'm serving veggie burgers instead of beef burgers. Can I serve them rare?"
  - Challenge study: does *E. coli* O157:H7 or *L. monocytogenes* grow in veggie burgers in refrigerated storage? How do they respond to heat on veggie burgers? Same as on beef?

HOW TO RUN A CHALLENGE STUDY

- Customer requirements have changed
  - "My biggest account wants kale mixed into my bagged salads."
  - First question: does kale introduce microbial safety or quality issues? *E. coli* O157:H7? *Salmonella*? Spoilage organisms like *Pseudomonas* or *Pectobacterium*?
  - Challenge study: are standard processes sufficient to control organisms present in the new mix? Wash, drying, MAP, cold chain, etc.

HOW TO RUN A CHALLENGE STUDY

- Establish an experimental product / test bed that will give meaningful results
  - Exactly like your product = narrowly applicable
  - Very UNlike your product = less applicable
- For organism(s) of concern, establish suitable test organism
  - Challenge studies with actual pathogens are great, not always practical
    - Live pathogens usually not allowed in a pilot plant or food facility
    - Can be difficult to obtain (Norovirus) or difficult to work with (Covid-19)
  - Surrogate selection is critical – more on this later from Dr. Lee

HOW TO RUN A CHALLENGE STUDY

- For organism(s) of concern, establish meaningful inoculation method
  - Spot inoculation mimics point-source contamination (e.g. bird droppings)
  - Dip inoculation mimics cross contamination (e.g. via wash tank, splashing)
  - Mix inoculation mimics formulation contamination (e.g. via ingredient)
- Inoculation method is key to meaningful results
- Inoculation intensity – a balancing act
  - Heavier inoculation level facilitates accurate counting, establishing efficacy of treatments
  - Lower inoculation levels can be more accurately reflect contamination level seen IRL
  - Treatment efficacy may be influenced by heavy vs. light inoculation

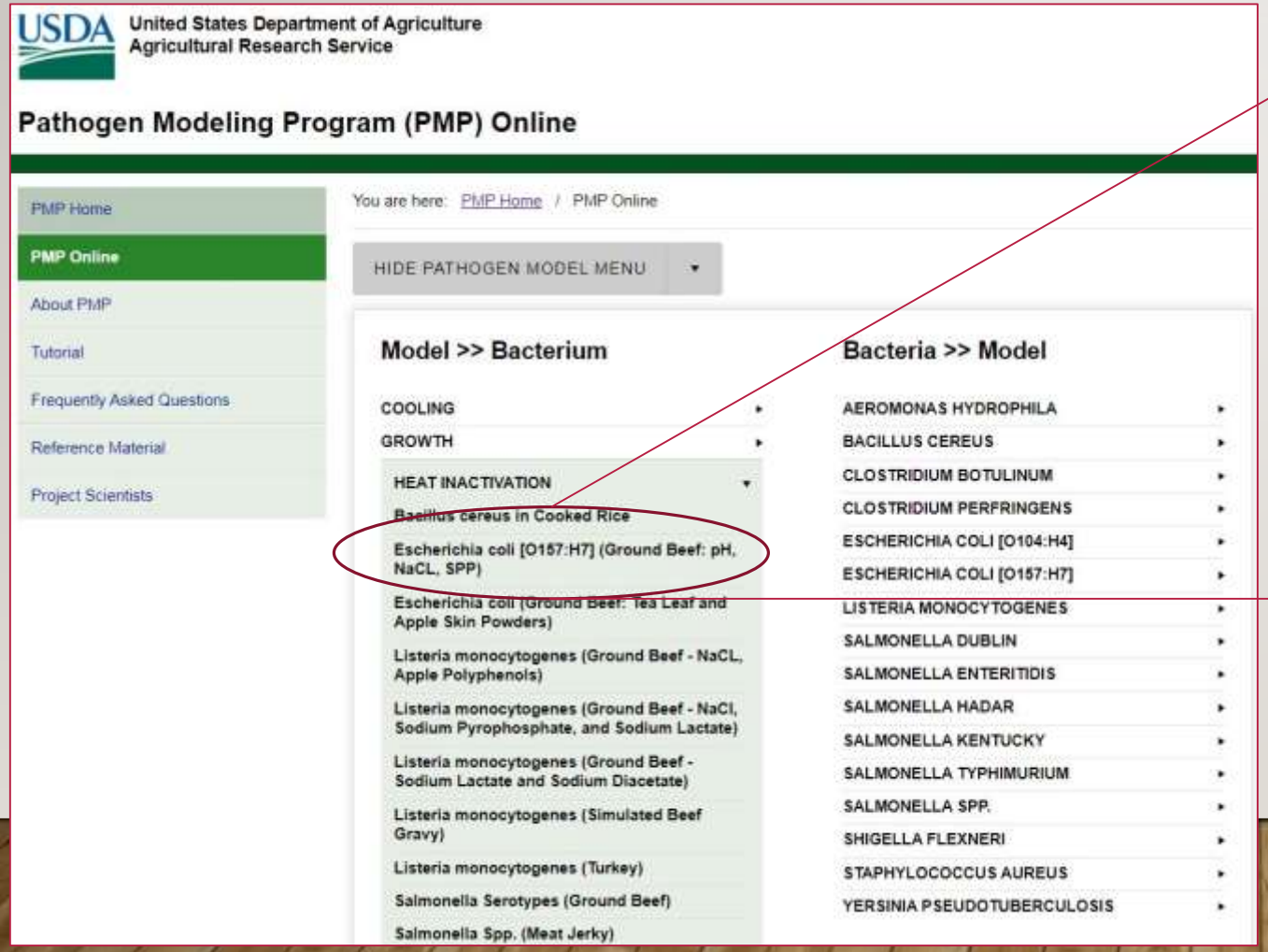
HOW TO RUN A CHALLENGE STUDY

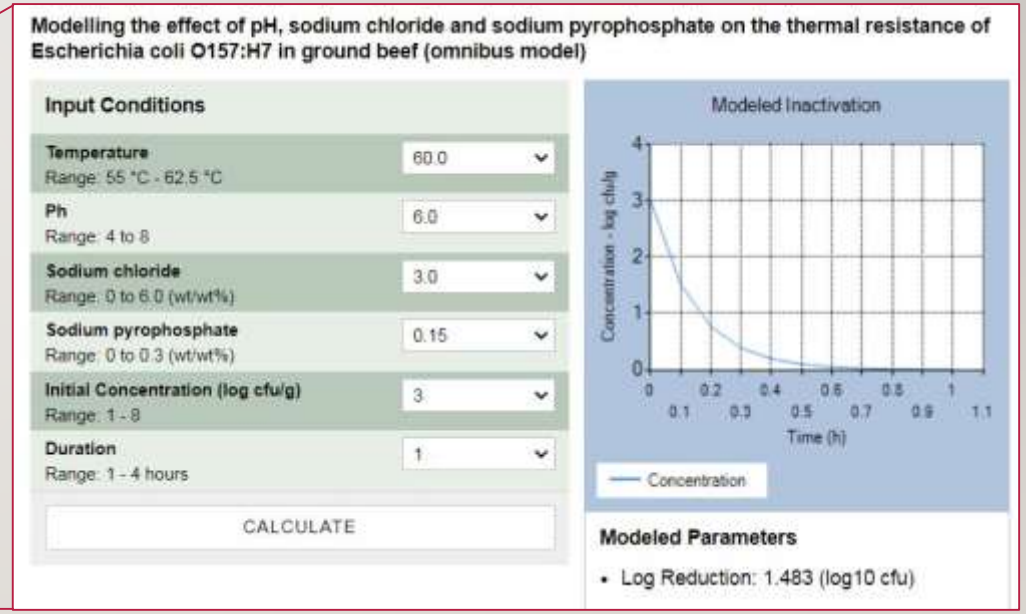
- Establish goal for test parameters
  - "How much kill can I get with treatments of X, Y, Z?"
  - "How should I vary the treatments to get desired level of kill?"
- Impact on sensory, texture, shelf life, consumer appeal

CHALLENGE STUDY – THE RESULTS

- Done properly, a challenge study will address key parameters to give meaningful, useful data
  - Tells you what the organisms are doing, under what conditions, and on what products
  - Verifiable from small scale to pilot scale to full process control data
- Data often incorporated into models describing organism responses to particular sets of conditions
  - Allows interpolation and (with caution) extrapolation
- Online tool: USDA-ARS Pathogen Modeling Program: https://pmp.errc.ars.usda.gov/pmponline.aspx

CHALLENGE STUDY – USING THE RESULTS
USDA-ARS PATHOGEN MODELING PROGRAM ONLINE





CHALLENGE STUDY – USING THE RESULTS

- USDA-ARS Pathogen Modeling Program: https://pmp.errc.ars.usda.gov/pmponline.aspx
  - Models for cooling, growth, heat inactivation, survival, transfer
  - Multiple organisms and isolates, under a wide range of conditions, for different commodities and formulations
- To be useful, results must be applicable to YOUR product, process, and target organism
- Customized challenge studies give an exact match and are exactly applicable
  - Also can be expensive, time consuming, tricky
- Interpolate, but mindfully! Extrapolate, but carefully!