Pathogen Modeling, Another Tool for the Regulatory Toolbox

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When Can Pathogen Modeling Help?

- Initial Validation
  - Development of process schedules
  - Confirmation of theoretical efficacy of controls
    - FSIS expects more than modeling alone to provide for the first part of initial validation (the scientific support)
- Corrective action in response to deviations
  - Particularly for relatively minor deviations
  - Good first step to evaluate worst case scenario

Modeling for Minor Deviations

- Most commonly used validated guidelines and regulatory process schedules have built in safety margins
  - Appendix B stabilization guideline as an example
    - Minor deviations under this guideline will not often result in prediction of more than 1 log growth of *Clostridium perfringens*
    - Modeling can be a quick means to establish the product is safe, based on the nature of the deviation

Modeling is not a Silver Bullet

- Modeling is one tool in the toolbox
  - Beneficial as a relatively quick tool used to assess the degree of concern about product safety
  - Understanding the appropriate use of models and how to pick the correct one for your process is key
    - Do the homework before there is a problem
      - Print and read the manual or model instructions
      - Practice using the model with data from your system