

# Inoculated Pack/Challenge Study Protocols



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## Background

- The restaurant and retail food store industry, routinely uses inoculation/challenge testing to determine whether a specific food requires time-temperature control for safety (TCS).
- When laboratory testing is used to support a change in how the product is handled in a food establishment (e.g., refrigerated to unrefrigerated holding, extending shelf life, etc..), this data is submitted to a state or local regulatory agency or directly to the FDA in the form of a variance application for approval.
- The submitter must ensure the study is appropriate for the food and pathogen of concern and incorporate the necessary elements into the study to yield a valid design and conclusion.

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## Background (cont'd.)

- The definition of potentially hazardous food (PHF) or time/temperature control for safety food (TCS food) was amended in the 2005 FDA Food Code to include pH and  $a_w$  interaction tables, allowing the hurdle concept to be used in the determination of whether TCS is necessary or not.
- When the pH and  $a_w$  Interaction Tables and the decision making framework are insufficient to show that a food does not require TCS, further product assessment using inoculation/challenge testing is likely required.

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Charge to the Subcommittee: Because of the many questions raised by regulatory and industry users on the definition of potentially hazardous food (PHF) or time/temperature control for safety food (TCS food), NACMCF is asked for its guidance to clarify these issues.

1. What are the appropriate criteria that must be considered for an inoculated pack/challenge study to determine if a food requires time/temperature control for safety (TCS)? For example, pathogen species/strain selection, use of surrogate organism, number of pathogen strains, inoculation level(s), incubation temperature(s), length of incubation/duration of study, food product physical properties, etc.

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## Charge to the Subcommittee (cont'd):

2. What are the appropriate uses of mathematical growth and inactivation models? Under what conditions can these models be used as a substitute for inoculated pack/challenge studies? Of the models currently available, which one(s) are most suitable for use and what are the limitations of these models?
3. What are the limitations for applying the results of an inoculated pack/challenge study on one food to another similar food?

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## Charge to the Subcommittee (cont'd):

4. Of the existing inoculated pack/challenge study protocols, *e.g.*, those published by the American Baking Association, NSF International, and others, which are most suitable for application to a wide variety of foods and what are the limitations of these protocols? Are there existing protocols that are appropriate for specific food/pathogen pairs?
5. Develop a decision tree to aid in the design of an appropriate inoculated pack/challenge study. Test or “desk check” the decision tree using the following five foods: meat filled puff pastry, (baked) cheese pizza, chopped lettuce, cheese (blocks or slices), and lemon meringue pie.

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## Charge to the Subcommittee (cont'd):

6. Identify the basic knowledge, skills, education, training, experience, and abilities necessary for a multidisciplinary work group or individual to be qualified to design, conduct and evaluate an inoculated pack/challenge study and the pursuant results.

Questions???