CFP Challenge Testing Worksheet to Determine Microbiological Stability of a Formulation

Protocol	Actual
Appropriate Study Design, Data Collection, and Data Interpretation Conducted by a Qualified Individual? (See Table 1 of the NACMCF Executive Secretariat. 2010 Parameters for Determining Inoculated Pack/Challenge Study Protocols. J. Food Prot. 73(1):140-202) as well as Institute of Food Technologists. 2001. Evaluation and Definition of Potentially Hazardous Foods. (IFT/FDA Contract No. 223-98-2333. Task Order No. 4 December 31.)	
Appropriate Challenge Microorganisms Selected? See Tables 4-1/6-1 of the (IFT Report and Table 2 and Appendix C of the NACMCF Report	
Proper Inoculum Level Used to Meet Objective? Typically, Between 2 and 3 log CFU/g	
Does Study Describe Preparation of Inoculum Using Appropriate Media and Under Conditions to Optimize Growth?	
Was Inoculation Method Used That Does Not Change the Critical Parameters of the Product Formulation Undergoing Challenge?	
Was Study Conducted for a Duration That Being at Least the Desired Shelf Life of the Product, plus an Additional Time of the Intended Shelf Life to Provide for Expected Consumer Consumption? See Section 10.0 Duration of Study and Sampling Intervals NACMCF Report (25-50%) as Well as NIST Handbook 130 E. Uniform Open Dating Regulation 3.3.1. Reasonable Period for Consumption. (30%).	
Was Each Key Factor Variable Tested that Controls a Product's Microbiological Stability Under Worst-Case Conditions?	
Did the Analysis Include the Supporting Data (Information Regarding the Product's Formulation, Types of Ingredients, Processing, and Final Packaging)?	
Did the Product Study Represent and Support the Conditions (Temperature, Packaging, Humidity, etc.) the Product Will Go Through at the Retail Level?	
Sample Analysis Were Duplicate and, Preferably, Triplicate Samples of Each Lot (at least two) Used? Were the Levels of Live Challenge Microorganisms Enumerated at Each Sampling Point?	
Was Appropriate Toxin Testing Performed at Each Time Point using the Most Current Validated Method? Were Uninoculated Control Samples Analyzed for Background Microflora at Each or Selected Sampling Points?	
Data Interpretation Once the Study is Completed, Was the Data Analyzed to See How the Pathogens Behaved Over Time (Died, Remained Stable, or Increased)? In the case of Toxin-Producing Pathogens, was any Toxin Detected Over the Designated Challenge Period?	
Pass/Fail Criteria Note: The Significance of a Population Increase Varies with the Hazard Characterization of Each Microorganism. See IFT Report, Part 9 of Chapter 9 Microbiological Challenge Testing. The Exclusive Use of Computer Models are Not Recommended as they Address and Model only Certain Pathogens, and Do Not Mimic the Environmental Conditions at Retail or the Growth of Bacteria in Real Food Systems.	

Note: This worksheet does not address the implementation of the product's handling once approved, as the local regulatory authority will likely require that procedures from the establishment also be submitted and implemented regarding the handling of the product as part of a variance or other approval.