Checklist for Retail Establishment Challenge Study for Extended Shelf Life or Holding Outside Temperature Control – Product not to be packaged

Section 1.0 – Laboratory Selection

YE S	N()	Does laboratory selection meet appropriate criteria from Section 1.0 of NACMCF document?
		(See Table 1 in the NACMCF document)

Section 3.0 – Factors related to tested product

Critical Physical Property	Range for Product (indicate NA if not applicable)	
Water activity (a _w)		
рН		
Salt content		
Moisture		
Other (including nitrites or inhibitors):		
Intended Conditions for Storage	Range for Product (indicate NA if not applicable)	
Storage temperature		
Storage shelf life		
Shelf life duration during challenge study		
YES NO Was product prepared and tested at intended conditions of use?		

Section 4.0 - Organism Selection

Use Table 2 and Appendix C from NACMCF document to determine answers

Pathogen (Expand rows as needed)	Growth in the a _w of food being tested?	Growth in the pH of food being tested?	Concern in the food product category?
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO

Section 9.0 – Sample Considerations

How many samples were analyzed initially and at required time intervals?				
YES	NO	Was sample replicated as required (2+ for most pathogens, 5+ for <i>C. botulinum</i>)		
YES	NO	Does lab provide sample preparation information that is appropriate for food being tested?		
YES	NO	Does lab provide information on enumeration of pathogens/measurement of toxins conducted using validated methods in a qualified lab? (NACMCF Appendix A)?		

Section 10.0 – Duration of Study and Sampling Intervals

YES	NO Does growth inhibition study provide adequate safety margin for shelf life?		
YES	NO	NO Were at least 5 to 7 sampling intervals done during challenge study?	
Maximum shelf life allowed based on study and safety margin:			

Section 11.0 – Interpreting Test Results (note that a product does not support pathogen growth if growth does not exceed the initial inoculum level by the limits listed below throughout the intended shelf life of the product and across replicate trial)

- Most foodborne pathogens: 1-log increase above the initial inoculum level
- S. aureus and B. cereus: 3-log increase above the initial inoculum level
- C. botulinum: No toxin should be detected in the product

Pathogen (Expand rows as needed)			Initial Inoculum level (CFU/g)	Highest Growth Level (CFU/g)	Total Growth (CFU/g)
YES	NO	Do results of	study meet PASS/FAIL cr	riteria in Section 11 of NACI	MCF document?
		S ON AREAS C	F STUDY THAT DO NO	OT MEET NACMCF CRITE	RIA (expand rows as
need	ed)				