Product Name :
DTN :
Study Title :

SELF-ASSESSMENT CHECKLIST FOR MODIFIED AND NON-STANDARD BIO-EFFFICACY TEST PROTOCOL PRE-APPROVAL

DOCUMENTARY REQUIREMENTS	YES	NO	REMARKS	FOR FDA USE ONLY
1. Letter of Intent				
2. Filled-Out Integrated Application Form with Signatures of Owner/ President/ General Manager and Authorized Representative				
3. Copy of Valid License to Operate				
4. Test Protocol				
4.1 Background				
4.1.1 Information on the Product				
• Product Owner				
• Product Classification				
• Formulation Type				
• Identity and concentration of the active ingredient/s				
• Available information on the efficacy of the active ingredient/s against intended target pest				
• Available information on the toxicity of the active ingredient/s, both acute and chronic toxicity				
• Available information on resistance and cross-resistance of target pests against the active ingredient/s				
• Information whether the test/s have been previously accepted by other regulatory agency				
4.1.2 Purpose of the proposed test				
• Specific claim of the household pesticide; includes: o field of use o mode of application o target pest/s o dilution rate o application rate o frequency of re-application				
4.1.3 Justification/Reason for the modified or non-standard protocol				
• Existing accepted protocol, if available				
• Compelling reason for the modification or use of non-standard test protocol				
4.2 Methodology				
4.2.1 Test Duration				

4.2.2 Test Insects					
• Species (in binomial nomenclature)					
• Source (i.e laboratory reared, wild-collected) o Rearing technique for laboratory-reared target insect/s including environmental conditions and food					
• Age and sex					
4.2.3 Positive Control					
• Registered HUP product with the same active ingredient/s or active ingredient belonging from the same chemical family					
• Include HSR number					
4.2.4 Negative Control					
4.2.5 Test Procedure including but not limited to:					
• Environmental Conditions					
• Acclimatization of Test Insect/s					
• Mode of application					
• Dilution Rate					
• Application Rate					
• Size of the test o Number of test insect/s per replicate o Number of replicates (min. of 3)					
• Test area / facility / equipment o For laboratory trial: include (a) Design of chamber including material and dimension, and (b) Cleaning/washing protocol o For field trial: include (a) Selection criteria for the test location, (b) Equipment design, and (c) Cleaning/washing protocol, (d) plot size					
• Schedule of observation					
• Efficacy Parameter					
• In case of modified protocol, include a description of the modifications made in their respective sections					
4.2.6 Statistical Analysis					
NOTE: For protocols with human subjects:					
• Selection Criteria					
• Informed Consent Form					
• Certification/Approval from a Research Ethics Committee					
4.3 References					

--- To be filled out by CCHUHSRR Personnel ---			
Pre-Assessor:		**Signature:**	
Position:		**Date:**	
Decision:	☐ Acceptance ☐ Non-Acceptance	**Remarks:**	