Appendix D: Test Kit Evaluation Submission Form

The applicant must fill out the submission form and provide it along with the submission packet. The information provided in the submission form will be used in creating the certificate if the test kit meets all GIPSA requirements; therefore, it is imperative that the form be filled out correctly. A fillable version of this form is available on the FGIS website.

Contact Information	**Clear Form**
Applicant (i.e., test kit manufacturer)	
Street Address	
City, State, Zip Code	
Contact Person	
Phone Number	
Email Address	
Billing Address (if different than manufacturer's address)	
City, State, Zip Code	

Test Kit Information	
Test Kit Name	
Product Identification Number	
Test Method Format	
Reader Name	
Reader Model or Identification Number	
Detection Method	
Upper Conformance Limit	
Additional Commodities (list in alphabetical order)	

Appendix D: Test Kit Evaluation Submission Form (continued)

Design Criteria and Performance Specification Check List	
The test kit meets the performance requirements and submission packet components are included.	**Initials**
Time for completion of analysis ≤ 30 minutes	
GIPSA reference method or equivalent used for reference analyses (validation report or literature reference provided if GIPSA reference method not used)	
Accuracy study for naturally contaminated wheat from 5.0 – 100 ppb ochratoxin A	
Additional accuracy data for optional extension of upper limit of conformance above 100 ppb ochratoxin A in wheat	
Data supporting accuracy of multiple ranges of quantitation	
Additional commodities – accuracy data; sample preparation and analytical procedure is described for each additional commodity (including grinding procedure); type of reference material is given (naturally-contaminated or standard-solution fortified)	
Use of the test kit does not expose the employees to toxic or hazardous substances higher than OSHA Standards per 29 CFR when used without a fume hood or respirator.	
Use of the test kit does not generate radioactive waste, P-listed hazardous waste, or hazardous waste listed for its toxicity characteristic as defined in 40 CFR	
Safety Data Sheets (SDS)	
Reader electromagnetic field study certification statement (renewals exempt if same reader)	
Temperature sensitivity study	
Shelf life study	
Certificates of analysis for reference materials	
Written test kit instructions (provided as Microsoft Word document)	
Method flow chart is included (optional)	
Protocol & Notification Agreement Statement signed by applicant	

Comments