United States Department of Agriculture
Grain Inspection, Packers and Stockyards Administration
Federal Grain Inspection Service

Directive 9181.2 03-22-11

PERFORMANCE VERIFICATION OF QUALITATIVE MYCOTOXIN AND BIOTECH RAPID TEST KITS

1. PURPOSE

This directive describes the Grain Inspection, Packers and Stockyards Administration (GIPSA) procedures for verifying the performance of qualitative mycotoxin and biotechnology rapid test kits.

This directive does not establish approval to use the test(s) for official purposes.

2. REPLACEMENT HIGHLIGHTS

This directive has been revised to reflect a change from event-based testing to protein-based testing for biotechnology rapid test kits. This directive also replaces Limit of Detection with Detection Threshold and added references to the GIPSA mycotoxin reference methods. This directive supersedes FGIS Directive 9181.2, dated 05-01-08.

3. BACKGROUND

To meet the grain industry's demand for accurate and reliable qualitative testing for mycotoxins and biotechnology-derived proteins, test kit manufacturers have asked GIPSA to provide a program to verify test kit performance claims and subsequently issue Certificates of Performance for test kits meeting these claims. In response to this request, GIPSA has established a program for verifying the performance of qualitative rapid test kits to detect the presence of mycotoxins or biotechnology-derived proteins in grains and oilseeds.

4. PROGRAM DEFINITIONS

Mycotoxins: Toxic substances produced by fungi (molds) growing on grain, feed, or food. These toxins may be hazardous to humans and/or animals.

Biotechnology-Derived Grains and Oilseeds: Grains and oilseeds that express proteins resulting from recombinant DNA technology (genetic engineering) to modify agronomic and/or quality characteristics.

Control Samples: Samples of grain or oilseeds that do not contain mycotoxins or biotechnology-derived grain and oilseeds, as applicable.

Fortified Samples: Samples of grain or oilseeds containing a predetermined concentration of mycotoxin(s) or biotechnology-derived grain due to the addition of (a) the corresponding fungus-infected grain or oilseed or (b) known quantities of the corresponding biotechnology-derived grain or oilseed, as applicable. The corresponding GIPSA mycotoxin reference method or equivalent should be used to determine the fortified concentration(s) of mycotoxin(s).

Detection Threshold: The lowest concentration of a mycotoxin or biotechnology-derived protein that can be reliably detected by a rapid test kit. This concentration will be specified by the manufacturer upon submission.

5. RAPID TEST PERFORMANCE EVALUATION PROGRAM

The Rapid Test Performance Evaluation Program established by GIPSA is a basic four step process where:

a. The rapid test manufacturer submits a data package supporting their claims.

b. The GIPSA staff reviews the data submitted by the manufacturer.

c. If the data package is complete and the claims of the rapid test are supported by the data, GIPSA conducts an in-house performance verification of the rapid test.

d. If the manufacturer's claims are verified by GIPSA’s in-house performance testing, a Certificate of Performance is issued to the manufacturer for the rapid test.

6. MANUFACTURER INFORMATION

a. DetectionThreshold.

The manufacturer is required to submit data that supports the claims they make regarding the rapid test.

(1) Mycotoxin Test Kits.

The test must reliably detect the presence of the mycotoxin(s) in samples of the corresponding fungus-infected grain/oilseed at the detection threshold claimed by the manufacturer. A GIPSA mycotoxin reference method or equivalent should be used to verify that the sample is fortified at the detection threshold.

(2) Biotech Test Kits.

The test must reliably detect the presence of the biotechnology-derived grain/oilseed at the detection threshold claimed by the manufacturer.

Since these tests are generally designed to detect the presence of a protein, and protein expression levels can vary significantly, the manufacturer should establish the detection threshold consistent with the lowest observed expression level.

b. General Information.

To submit a rapid test to GIPSA for performance verification, the manufacturer must submit the following information to the Test Kit Program Manager.

- Manufacturer name and address.
- Manufacturer contact person.
- Telephone number.
- Fax number.
- E-mail address.
- Test Format: Lateral flow strip, microtiter well assay, or other (specify).
- Matrix: Corn, soybeans, other (specify).
- Mycotoxin(s) detected. (applicable to mycotoxin test kits only)

- Protein(s) detected and the corresponding event(s) (applicable to biotech test kits only).

- Detection threshold.

- User instructions for the rapid test kit.

Send this information along with the testing data as specified in section 7 below to:

Test Kit Program Manager
USDA, GIPSA, TSD
10383 North Ambassador Drive
Kansas City, MO 64153-1394

7. MANUFACTURER DATA SUBMISSION

To support claims with respect to the particular rapid test, the manufacturer is required to submit the following data to GIPSA:

a. Control Samples.

One hundred twenty (120) independent analyses, using three different test lots, 40 samples for each lot. All test results must be negative for the mycotoxin or biotechnology-derived protein of interest.

b. Fortified Samples.

One hundred twenty (120) independent analyses, using three different test lots, 40 samples for each lot, at the claimed detection threshold. All test results must be positive for the mycotoxin or biotechnology-derived protein of interest. For mycotoxins, the GIPSA mycotoxin reference method or equivalent should be used to set the concentration(s) at the detection threshold.

c. Performance of Rapid Test at 18^{o} C and 30^{o} C.

Data must be provided demonstrating reliable performance of the test at 18^{o} C and 30^{o} C. Samples, equipment, and testing materials must be equilibrated at the testing temperature for one hour prior to conducting the analyses.

(1) Control sample analyses at 18^{o} C.

Fifteen (15) independent analyses. All test results must be negative for the mycotoxin or biotechnology-derived protein of interest.

(2) Fortified sample analyses at 18° C.

Fifteen (15) independent analyses. All test results must be positive for the mycotoxin or biotechnology-derived protein of interest.

(3) Control sample analyses at 30° C.

Fifteen (15) independent analyses. All test results must be negative for the mycotoxin or biotechnology-derived protein of interest.

(4) Fortified sample analyses at 30° C.

Fifteen (15) independent analyses. All test results must be positive for the mycotoxin or biotechnology-derived protein of interest.

d. Cross reaction with other biotechnology-derived proteins (biotech test kits only).

Data from five (5) independent tests of all other biotechnology-derived proteins in commercial production in the U.S. demonstrating the test is specific for the protein of interest, but not necessarily trait-specific. All tests must be negative for test samples that do not contain the target protein. If multiple events express the same protein, these events and their corresponding protein expression levels must be indicated on the submission data package and in the final instructions included in the manufactured test kit.

For verification of biotech test kits, reference material (whole kernel or seed) is required to perform the verification. In the event that GIPSA does not have this reference material available, the test kit manufacturer may be asked to obtain reference material from the appropriate life science company in order to verify the claims of the kit. In this instance, GIPSA reserves the right to characterize the integrity of the reference material by appropriate laboratory analysis.

8. GIPSA REVIEW AND PERFORMANCE VERIFICATION

Upon receipt of the data submission from the manufacturer, GIPSA will:

- Review the data submission for completeness and compliance with GIPSA performance standards as stated above.
- Advise the manufacturer that the test met or did not meet the performance specifications.

If the test kit meets all performance specifications, GIPSA will contact the manufacturer and identify a mutually agreeable date for the manufacturer to train GIPSA staff in the operation of the test. While training of GIPSA staff is advisable, it can be waived at the manufacturer's discretion.

The performance verification will consist of the GIPSA analysis of control and fortified samples as specified below:

(1) Control Samples.

Thirty (30) independent analyses will be conducted, using three different test lots, ten samples for each lot. All test results must be negative for the mycotoxin or biotechnology-derived protein of interest.

(2) Fortified Samples.

Thirty (30) independent analyses will be conducted, using three different test lots, ten samples for each lot, at the claimed detection threshold. All test results must be positive for the mycotoxin or biotechnology-derived protein of interest. For mycotoxin tests, GIPSA reference methods will be used to set the mycotoxin concentration(s) at the detection threshold.

If the test kit fails the performance verification, the test kit must be resubmitted with new supporting performance data.

9. EVALUATION SERVICE FEE

Section 800.71(a) of the regulations under the USGSA provide for a miscellaneous service fee for specialized services, such as performance evaluations. GIPSA will assess a service fee to test kit manufacturers for each performance evaluation conducted by GIPSA personnel. The fee is applicable to all kits submitted to GIPSA for evaluation, regardless of whether the kits meet or do not meet the manufacturer's performance claims.

10. CERTIFICATE OF PERFORMANCE

A rapid test that successfully demonstrates conformance with the manufacturer's claims will be awarded a Certificate of Performance. The Certificate of Performance automatically expires three (3) years from the date of issue. The manufacturer will be required to resubmit new performance data to GIPSA prior to the expiration date to have the Certificate of Performance renewed for an additional three years.

GIPSA reserves the right to rescind the Certificate of Performance if:

- The manufacturer fails to notify GIPSA of changes or alterations to the test (as per Section 11 of this directive), or
- The test is found to produce invalid results identified by users, or through some other program.

11. MANUFACTURER NOTIFICATION RESPONSIBILITIES

Any manufacturer of a rapid test that has received a GIPSA Certificate of Performance must notify the Test Kit Program Manager in writing when any changes or alterations are made to the rapid test (including changes in chemical reagents, equipment, or procedures). Failure to notify GIPSA of these changes will constitute grounds for immediate withdrawal of the GIPSA Certificate of Performance. The Test Kit Program Manager will determine the significance of any changes and advise the manufacturer if it will be necessary to prepare another data submission to maintain the Certificate of Performance.

12. CONTACT INFORMATION

Direct any correspondence regarding this Program to the GIPSA Test Kit Program Manager:

- E-mail: timothy.d.norden@usda.gov
- Mail Address:

  Test Kit Program Manager
  USDA, GIPSA, TSD
  10383 North Ambassador Drive
  Kansas City, MO 64153-1394

/s/

David B. Funk, Acting Director
Technical Services Division