United States Department of Agriculture
Agricultural Marketing Service
Federal Grain Inspection Service

Directive

9180.90 June 1, 2026

NATIONAL MYCOTOXIN QUALITY ASSURANCE PROGRAM

CONTENTS

1. PURPOSE

This directive establishes the National Mycotoxin Quality Assurance Program (NMQAP) under the authority of the United States Grain Standards Act (USGSA) and to meet the requirements of 7 CFR 800.216. The program consists of mycotoxin proficiency testing and inspection monitoring. This document outlines roles and responsibilities within the Federal Grain Inspection Service (FGIS) and its official agencies as they pertain to this program and describes the procedures for participation.

2. POLICY

Field offices and official agencies that offer mycotoxin testing are required to participate in the proficiency tests and inspection monitoring in accordance with the procedures provided herein. This directive is effective beginning **June 1, 2026**.

3. BACKGROUND

Mycotoxins are secondary metabolites produced by certain species of fungi and some mycotoxins pose a significant health hazard to humans and animals. As a result of their toxicity, global regulations have been established for mycotoxins and they have become important factors in the trade of grain.

FGIS provides official mycotoxin testing services at field locations throughout the United States for grain, oilseeds, and processed-grain commodities.

Currently, testing services are provided for aflatoxins (AFLA), deoxynivalenol (DON), fumonisins (FUM), ochratoxin A (OCHA), and zearalenone (ZEAR).

A national quality assurance program is being established with issuance of this directive and will initially consist of proficiency testing and inspection monitoring for AFLA and DON only. Other mycotoxins may be added later with advanced notice to participants and revision of this directive.

Proficiency Testing (PT) is a process designed to evaluate a laboratory's performance and testing accuracy for specific methods, matrices, and analytes, as compared to other laboratories. PT is important for ensuring consistency in laboratory performance and for maintaining reliability and high standards. Inspection monitoring is a direct comparison of a laboratory's performance with the FGIS laboratory and functions to provide ongoing feedback with respect to a laboratory's accuracy and precision.

4. DEFINITIONS

Test material. The material that is distributed to proficiency test participants.

Distribution Unit. A packaged portion of the test material used for distribution to proficiency test participants.

Test portion. The amount of test material in a distribution unit that is used for a single mycotoxin determination.

Round. A single distribution of test materials to participants in a proficiency test.

Specified Service Point (SSP). A location providing official service.
Each SSP has a unique identification number issued by FGIS.

5. RESPONSIBILITIES

a. Technology and Science Division (TSD).

- Serve as the proficiency test manager.
- Provide a summary report for each proficiency test.
- Configure the FGIS Quality Assurance and Control (QAC) application for selection of monitoring samples.
- Provide reference testing for comparison to inspection monitoring results.
- Furnish feedback to each field office or official agency concerning the accuracy of monitored results. Monitor reports will also be provided to the Quality Assurance and Compliance Division (QACD)and supervising field offices.
- Assist the participants in troubleshooting problems related to mycotoxin results and developing an action plan to resolve the problem or minimize the impact through better management practices.
- Upon request, dispatch a TSD member for on-site assistance in troubleshooting, training, and resolution of issues.
- Annually review the efficacy of the NMQAP and make recommendations for improvement.

b. Field Offices and Official Agencies.

- Participate in both proficiency testing and inspection monitoring while approved or licensed to provide official mycotoxin testing.
- Ensure each SSP under their supervision (that conducts mycotoxin testing) is participating.
- Register for participation with TSD by providing the following information:
    - Field office or official agency name.
    - Specified Service Point Number.
    - Shipping Address.
    - Person’s Name serving as Point of Contact.
    - Phone Number.
    - Email Address.
- Review reports, investigate, and take corrective action when results are indicative of a problem.

c. Quality Assurance and Compliance Division (QACD).

- Review reports from these programs.
- Incorporate information from these programs into performance evaluations of field offices and official agencies.

6. PROFICIENCY TESTING

TSD will notify all registered participants at least two weeks in advance of the anticipated timeframe for the next round of proficiency testing.

Participants are required to analyze the test materials and report results within two weeks of the date of shipment.

Test materials will be distributed by TSD to participants. The test materials will be the primary commodities, corn or wheat, dependent on the mycotoxin of interest.

Instructions for testing and reporting will be included with the test materials.

Results submitted after the due date may not be included in the report.

TSD will analyze the data and issue a report for each round approximately one month after submission closes to the following parties:

- SSP Point of Contact (POC).
- All Division Directors.
- All Field Office Managers.
- QACD.

a. Test Materials.

Naturally contaminated materials will be used.

Prior to distribution, each test material will be determined to be sufficiently homogenous so that the subsampling variability does not significantly affect the results of the proficiency test round.

In addition, each test material will be determined to have a mean mycotoxin concentration within a range targeted by TSD and of relevance to the trade.

Test materials will be sealed in Mylar foil packets and labeled with the sample ID.

To verify test material stability, TSD will analyze stored test portions of each test material covering the timeframe of the round (shipment date to reporting deadline).

The test portions used for stability testing will be stored at ambient room temperature (68–74°C).

b. Assigned Value.

The assigned value will be the mean concentration determined by replicate analysis of the test material by the FGIS reference method. The assigned value will not be disclosed to participants until after the reporting deadline.

c. Performance Evaluation.

The z-score will be used for assessing participant performance. The z-score is the number of standard deviations between the participant's result and the assigned value. Z-scores will be determined using Equation 1.

Equation 1. Calculation of the Z-Score for Proficiency Testing.

$$Z\text{-}Score = \frac{(x_{ssp} - x_A)}{(0.01 x_A \, PRSD_R)}$$

X_{SSP} = SSP result (ppb aflatoxin or ppm DON).

X_A = assigned value (ppb aflatoxin or ppm DON).

$PRSD_R$ = Predicted relative standard deviation under reproducibility conditions expressed as a percentage and equal $2 \cdot C^{-0.1505}$ where C is the concentration expressed as a mass fraction (Example: 5.0 ppm DON = $5.0 \cdot 10^{-6}$ g DON per gram of sample).

The warning limits will be set at z-score ± 2.

The action limits will be set at z-score ± 3.

Each participant is responsible for reviewing results, assessing their performance, and taking appropriate corrective action if a problem is indicated.

A problem is indicated when multiple results from a field office or agency fall outside warning limits but within action limits, or if any result exceeds the action limits. TSD will give technical guidance for resolving issues.

d. Confidentiality.

The report issued by TSD will track results by Lab ID # assigned by TSD. The POC for the lab will be notified of their Lab ID #. Furthermore, TSD will issue a key containing all participants and their IDs to FGIS management.

7. INSPECTION MONITORING

a. Sample Selection.

The QAC application will be used to select samples.

b. Sample Shipment.

Each sample must be sealed in a plastic bag that is marked with the sample ID using a permanent marker. Sample material needed for aflatoxin monitoring should be greater than or equal to 125g and taken from the originally tested ground material portion. Sample material needed for DON monitoring should be greater than or equal to 75g and taken from the originally tested ground material portion.

Ensure that a legible and complete QAC Sample Ticket accompanies each sample. The QAC Sample Ticket should not be placed inside the sample container.

Retain a sub-portion for the file sample according to Mycotoxin Handbook Section 4.4 Sample Portions, a. Sub-portions.

Ship samples separately from those for other programs at the National Grain Center (NGC).

All nonfederal offices should ship samples using UPS 2nd Day Air service and charge shipping costs to TSD. Contact TSD to obtain the UPS account code. All federal offices should use UPS 2nd Day Air service, but charge shipping costs to their appropriations account (56) using their own UPS code.

Ship samples to the following address:

Mycotoxin Inspection Monitoring
USDA FGIS TSD
10383 North Ambassador Drive
Kansas City, Missouri 64153-1394

c. Performance Evaluation.

TSD will sieve test each sample to verify it meets the requirement stated in the FGIS Mycotoxin Handbook.

Samples will be further ground in cases where they do not meet the minimum requirement of the FGIS reference method prior to analysis.

The following information will be recorded and issued by email in the weekly reports.

- Sample ID.
- Date of Analysis by Field Office / Official Agency.
- Sieve Test Result.
- SSP Mycotoxin Result.
- TSD Mycotoxin Result.
- Z-Score.

Reports will include results in tabular format along with a graph of z-scores plotted by date of analysis by SSP for the last six months.

The z-score is the number of standard deviations from the assigned value.

The FGIS reference method result will serve as the assigned value.

The z-score will be calculated using Equation 2, which accounts for the random error of the reference method, since only one reference measurement is performed.

Equation 2. Calculation of the Z-Score for Inspection Monitoring

$$z\text{-}score = \frac{(x_{ssp} - x_A)}{[0.01x_A(PRSD_R{}^2 + RSD_A{}^2)^{0.5}]}$$

X_{SSP} = SSP result (ppb aflatoxin or ppm DON).

X_A = assigned value (ppb aflatoxin or ppm DON).

$PRSD_R$ = Predicted relative standard deviation under reproducibility conditions expressed as a percentage and equal $2 \cdot C^{-0.1505}$ where C is the concentration expressed as a mass fraction (Example: 5.0 ppm DON = $5.0 \cdot 10^{-6}$ g DON per gram of sample).

RSD_A = Estimated relative standard deviation of the reference method expressed as a percentage.

The warning limits will be set at z-score ± 2.

The action limits will be set at z-score ± 3.

Each participant is responsible for reviewing results, assessing their performance, and taking appropriate corrective action if a problem is indicated.

A problem is indicated if more than one in 20 consecutive results exceeds the warning limits but is within the action limits, or if any result exceeds the action limits. TSD will give technical guidance for resolving problems upon request.

An annual report summarizing individual and system-wide performance may be issued by TSD.

d. Confidentiality.

The weekly reports issued by TSD will track results by SSP#. For the annual summary report, a separate key will be provided to FGIS management.

8. QUESTIONS

Direct inquiries regarding the NMQAP to the Analytical Chemistry Branch.