March 24, 2021

U.S. Department of Agriculture
Agricultural Marketing Service
1400 Independence Ave., S.W.
Washington, D.C. 20250

RE: Docket AMS–FGIS–20–0061; Mycotoxin Test Kit Design Specifications and Performance Criteria

The National Grain and Feed Association (NGFA), the North American Export Grain Association (NAEGA) and the North American Millers Association (NAMA) appreciate the opportunity to submit this joint statement in response to the request for comments by the Agricultural Marketing Service (AMS) concerning its proposed changes to the criteria for mycotoxin test kit design specifications and performance criteria published in the December 18, 2020 edition of the ***Federal Register***.

NGFA, established in 1896, comprises more than 1,050 member companies that operate more than 7,000 facilities and handle more than 75 percent of the U.S. grain and oilseed crop. NGFA's membership encompasses all sectors of the industry, including country, terminal, and export grain elevators; commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also has strategic alliances with NAEGA and the Pet Food Institute. In addition, affiliated with the NGFA are 33 state and regional grain and feed trade associations.

NAEGA, a not-for-profit trade association established in 1912, consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the agri-bulk products international trading industry. NAEGA members are exporters

of and serve the vast majority of all U.S. grain and oilseeds in international markets. NAEGA's mission is to promote and sustain the development of commercial export. Through a reliance on member action and support, NAEGA acts to accomplish its mission in markets throughout the world.

NAMA represents millers of wheat, corn, oats and rye across the continental United States, Puerto Rico, and Canada. Its members take raw grain and, through grinding and crushing, create flour and other products used to make favorite foods, such as bread, cereals, pasta, cookies, cakes, and snack foods.

NGFA, NAEGA and NAMA share the belief that the Official grain inspection and weighing system continually must improve if it is to remain relevant and provide the service needed by the grain industry in the ultra-competitive marketplace in which the industry operates. The Official inspection and weighing system is designed to provide uniform service regardless of the provider. This uniformity should extend beyond inspection results to include all aspects of customer service including test kits.

NGFA, NAEGA and NAMA also commend the Federal Grain Inspection Service (FGIS) for coordinating the March 8 "listening session" with the test kit manufacturers and industry representatives as a means for them to provide feedback on the proposed changes highlighted in the ***Federal Register*** notice, followed by questions and comments from FGIS staff. These types of forums are useful to help both the agency and stakeholders have a better understanding of the scope, intent and potential impact of the proposals which can then lead to both constructive feedback and analysis moving forward.

Subsequently, the NGFA, NAEGA and NAMA recommend that the AMS consider our recommendations which suggest a greater focus on research into reducing other sources of variation that can impact repeatability of results. Further, we strongly support the technical comments on the modifying the performance test criteria submitted individually by the following companies that manufacture, market, or support rapid diagnostic test kits for the detection of harmful mycotoxins in grains and oilseeds:

- Charm
- Envirologix
- Neogen
- R-Biopharm
- Romer

Overview

AMS is proposing to tighten the acceptance tolerance for performance verification for all mycotoxins that can be performance verified i.e., approved by the FGIS including: aflatoxin, deoxynivalenol, fumonisin, ochratoxin A, and zearalenone and increase the testing range of two mycotoxins, OTA and zearalenone. This proposed change is in response to two resolutions that were submitted at the FGIS Grain Inspection Advisory Committee in September 2018.

Resolutions:

1. *The Advisory Committee urges FGIS to continue to identify causes of variation in mycotoxin testing and to develop a comprehensive plan to address these causes.*

2. *The Committee requests FGIS to investigate certifying and reporting at lower levels than the current limit of quantitation, and report back to the Committee.*

At the next FGIS Grain Inspection Advisory Committee meeting in September of 2019, the Agency provided an update on progress on the resolutions made in September 2018. A summary of the update is as follows:

Variation

- Five areas of variation identified
    - Analyst proficiency
    - Analytical method performance (i.e., test kit performance)
    - Number of performance verified test kits (i.e., too many test kits)
    - Quality control at the local level
    - Sample drawing

The proposed rule only addresses one of the five sources of variance, analytical method performance, that is identified in their own research. However, it is well known that grinding, sample size and extraction can play a large role in the testing process. While all five of the sources of variance are of importance, as you can see below, our comments focus on quality control at the local level and sample drawing.

Thus, while the scope of the standard is limited to the analytical method of performance, the NGFA, NAEGA and NAMA strongly encourage the FGIS to consider the impact that griding, sample size and extraction processes can have on the test kit performances. Specifically, the FGIS should examine synchronizing each factor for both performance testing and at the field level. Further, the NFGA, NAEGA and NAMA look forward to working with FGIS on addressing each of these issues outside the scope of the proposed rule, if necessary.

Performance Verification Procedures vs. Testing Procedures

To achieve lower levers in mycotoxin detection, FGIS feels the right way to do that is to change the limit of quantitation in the program, set a new criterion, and then test kits to verify that can perform properly at those lower levels. It is possible, test kits may not be able to perform accurately at the lower level.

<u>Limit of Detection</u>

- Limit of quantitation (per FGIS report)– Lowest level of any method, where you have acceptable accuracy and precision in the test results;
- Limit of detection (per FGIS report) – Lowest level where we know that particular mycotoxin is present in the sample with high confidence (usually, 95%); and

- Limit of quantitation in the FGIS test kit evaluation program is the lowest level that FGIS establishes for the test kit manufacturers to give them the accuracy and precision. FGIS then tests the kit at that levels to confirm that it can perform at that level i.e., Performance Verification

Grinding and Homogenizing Sample Materials

Performance Verification – All commodities used in the performance studies must be ground so that at least 95% passes through a U.S. Standard No. 20 sieve and mixed thoroughly to ensure homogeneity prior to removing samples for testing.

Link to Performance Verification Procedure for Aflatoxin (Grinding and homogenization procedures in the Performance Verification procedures are the same for all 5 mycotoxins)

Testing Procedures – Unless otherwise stated in the FGIS-issued mycotoxin test kit instructions, the minimum quantity of ground grain (coarse and small grains) that should pass through a No. 20 sieve is 60 percent.

Link to Mycotoxin Handbook, which includes the requirements for checking particle size (pg. 4-9)

It is well known that grind consistency can have a (large) impact on test results. If that is the case, why does FGIS require one particle size (grind consistency) for performance verification, and something different in the official testing procedures?

Sample Testing Physical Size
Physical sides of all seeds being tested for mycotoxins are different. This results in a different number of seeds being present in any given sample being tested. Research is needed to determine if having the same sample testing size for all commodities (with the exception of DON, where a large corn sample is considered) can impact test variability.

Another factor to consider is where the sample itself is collected. The consistency of the sample can vary whether it is probed from a truck or automatically extracted from a bin after it has already been collected and moved via conveyor, rail, or barge.

Extraction
The time and how hard a sample is shaken can have an impact on test results. FGIS currently does not have set requirements for time/vigor for sample shaking. While this will be more test kit specific, perhaps FGIS could create some guidance or recommendations on extraction practices.

With additional sources of error from particle size (grind consistency), Sample testing size (potentially), and extraction (shake time and vigor), reducing performance verification acceptance tolerance:

- Will not sufficiently address testing variability

- May not be technically possible (without significantly increases development costs, which will be passed on to purchasers of test kits)
- Will not necessarily address the need for limits of quantitation to be adjusted down

Additional consideration should be given to the upper limit of quantitation currently required for a test kit to be performance verified. Specifically, is there a commercial need to have DON up to 30 ppm, fumonisin up 100 ppm, OTA up to 100 ppb, and zearalenone up to 1,000 ppm. If test kit manufacturers were not required to develop kits at the upper ranges, it is possible some of the variation could be reduced by focusing technical improvements at the lower levels. Another alternative would be to not require test kit manufacturers to have their test kits performance verified to the entire range. For example, for a test kit to be performance verified for aflatoxin, the kit must meet the acceptance tolerances from 5 ppb – 300 ppb. There is not an option for a kit manufacturer to only get performance verified to 5 ppb and 20 ppb, for example.

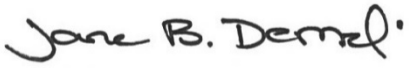
Conclusion

For the reasons cited herein, NGFA, NAEGA and NAMA urge the AMS to incorporate both the recommendations of the aforementioned mycotoxin test kit manufacturers and our proposals on sample extraction including particle size, sample size and shaking vigor. Each factor will play a larger role in increasing the accuracy of the testing in the field.

Sincerely,

Michael Seyfert
President and Chief Executive Officer
National Grain and Feed Association

Gary C. Martin
President and Chief Executive Officer
North American Export Grain Association



Jane DiMarchi
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