



Agricultural Marketing Service

[Doc No. AMS-FGIS-20-0061]

Mycotoxin Test Kit Design Specifications and Performance Criteria

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) evaluates the conformance of mycotoxin test kits to AMS-established design specifications and performance criteria. Only test kits that conform to all of the AMS requirements are approved for the official testing of grains and related commodities. AMS proposes to make several changes to the existing test kit criteria to improve testing services and better facilitate domestic and international trade. AMS is seeking public comment on the proposed changes to the criteria.

DATES: Comments are due by **[INSERT 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: The current criteria documents subject to the changes in this notice are available for review at <https://www.ams.usda.gov/services/fgis/standardization/tke>. Additional technical information regarding the proposed changes can be found at <https://www.ams.usda.gov/sites/default/files/media/technical-doc-frn-ams-fgis-20-0061.pdf>.

To submit Comments: Go to Regulations.gov (<http://www.regulations.gov>). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at <http://www.regulations.gov> and should reference the document number and the date and page number of this issue of the Federal Register. All comments submitted in response to this notice will be included

in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR MORE INFORMATION CONTACT: Thomas A. Weber, Analytical Chemistry Branch Chief, Technology and Science Division, Federal Grain Inspection Service, AMS, USDA, 816-891-0449, Thomas.A.Weber@usda.gov.

SUPPLEMENTARY INFORMATION: Mycotoxins are toxic chemicals produced by certain fungal species under favorable environmental conditions. Regulators have set maximum allowable concentration levels for specific mycotoxins in food and feed to ensure the safety of consumers. Mycotoxin levels are a critical factor in the trade of grain and quantitative mycotoxin testing is an integral part of buyer-seller contract specifications.

Under the authority of the United States Grains Standards Act (7 USC 71–87k), as amended, and the Agricultural Marketing Act of 1946 (7 USC 1621–1627), as amended, AMS provides official mycotoxin testing services throughout the United States for domestic and export grains, oilseeds, and processed-grain commodities. Official testing services are provided for aflatoxins, deoxynivalenol, fumonisins, ochratoxin A, and zearalenone. Testing at field locations requires rapid, inexpensive, and accurate methods to effectively assess US grain quality. An essential part of ensuring the quality of official mycotoxin testing is the AMS test kit evaluation program, through which test kits are evaluated and certified for conformance to specific criteria. Only test kits having AMS certification are approved for official mycotoxin testing.

AMS establishes the test kit performance criteria and periodically updates them to improve testing accuracy and to meet the official mycotoxin testing program's operational needs. AMS last updated the criteria in 2016. AMS proposes to update the test kit

performance criteria with the following changes in 2021. AMS is seeking comments on the impact of making these changes.

Minimum Ranges of Conformance

For each mycotoxin, AMS has established a minimum range of concentrations that must be covered in the test kit's scope. The test kit must conform to the AMS accuracy requirements throughout this range. AMS proposes to expand the minimum ranges of conformance for fumonisins, ochratoxin A, and zearalenone test kits to meet the current and anticipated testing needs of the grain industry.

The US Food and Drug Administration has set the highest industry guidance level for fumonisins in corn at 100 parts-per-million (ppm). As a result, AMS proposes to expand the current minimum range of conformance from 0.50–30 ppm to 0.50–100 ppm so that it includes this highest guidance level.

Since the measurement of mycotoxin concentrations is not exact, multiple measurements will have results that vary by some amount. To ensure a mycotoxin concentration is below the maximum level allowed, there is a need to measure sufficiently below that level, considering the expected variation in results. For this reason, AMS proposes to expand the minimum ranges of conformance for ochratoxin A and zearalenone test kits to lower concentrations than currently required.

Codex Alimentarius, an internationally recognized food safety standard setting body, recommends a maximum of 5 parts-per-billion (ppb) ochratoxin A in wheat, barley, and rye. Therefore, AMS proposes to expand the minimum range of conformance for ochratoxin A from 5.0–100 ppb to 1.0–100 ppb. AMS is interested in comments on whether the maximum conformance limit should also be changed from 100 ppb to 20 ppb, resulting in a narrower minimum range of conformance (i.e., 1.0–20 ppb).

International regulators, including the European Union (EU) have established maximum levels for zearalenone at 100 ppb in cereals and other grains. To test

sufficiently below this regulatory limit, AMS proposes to expand the minimum range of conformance from 100–1000 ppb to 20–1000 ppb.

Evaluation of Mycotoxin Test Kit Accuracy

To evaluate test kit accuracy, AMS requires analyses of reference materials to be performed at different concentrations across the range of conformance. At least 95% of these individual results must be within the acceptable range for each of the tested concentrations to meet AMS accuracy requirements. AMS proposes to change the way the acceptable ranges are calculated to align with international standards for evaluating method performance. Tables 1–5 compare the current acceptable ranges with the revised ranges based on the proposed method. The actual ranges may differ slightly from the listed ones, because results from the certification of reference materials would be included in determining the ranges. The proposed change will require greater accuracy from the test kits. Test kit manufacturers and other interested parties are encouraged to review the additional technical information, which serves as the basis for these changes at <https://www.ams.usda.gov/sites/default/files/media/technical-doc-frn-ams-fgis-20-0061.pdf>.

Table 1 – Aflatoxins

Aflatoxins (ppb)	Acceptable Range (ppb)	
	Current	Proposed
5.0	2.5–7.5	3.5–6.5
20	12–28	14–26
100	68–130	69–130
300	200–400	220–380

Table 2 – Deoxynivalenol

Deoxynivalenol (ppm)	Acceptable Range (ppm)	
	Current	Proposed
0.50	0.30–0.70	0.38–0.62
2.0	1.5–2.5	1.6–2.4
5.0	4.0–6.0	4.1–5.9
30	24–36	26–34

Table 3 – Fumonisin

Fumonisin	Acceptable Range (ppm)
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(ppm)	Current	Proposed
0.50	0.32–0.68	0.38–0.62
2.0	1.4–2.6	1.6–2.4
5.0	3.7–6.3	4.1–5.9
30	22–38	26–34
100	74–130	89–110

Table 4 – Ochratoxin A

Ochratoxin A (ppb)	Acceptable Range (ppb)	
	Current	Proposed
1.0	-	0.69–1.3
5.0	3.0–7.0	3.5–6.5
20	12–28	14–26
100	60–140	69–130

Table 5 – Zearalenone

Zearalenone (ppb)	Acceptable Range (ppb)	
	Current	Proposed
20	-	14–26
100	50–150	69–130
250	150–350	180–320
1000	600–1400	780–1200

Number of Readers

Mycotoxin concentrations are determined by an electronic instrument, often referred to as a “reader” by test kit manufacturers and users. AMS has observed variation in test results during side-by-side comparisons of identical reader models. Therefore, AMS proposes to use three separate readers during the evaluation process.

Test Kit Manufacturer Analysts

AMS proposes to update the criteria documents to allow up to two analysts from the test kit manufacturer to participate in the performance verification study conducted at the AMS facility. Participation by the test kit manufacturer promotes transparency and trust in the program.

Extraction Method

Each mycotoxin has one or two primary grains, which must be included in the scope of the test kit. AMS identifies a primary grain based on the known occurrence of

the mycotoxin and the frequency of official testing requests. Table 6 shows the list of primary grains by mycotoxin.

Table 6 – List of Primary Grains by Mycotoxin

Mycotoxin	Primary Grain(s)
Aflatoxins	Corn
Deoxynivalenol	Corn and Wheat
Fumonisin	Corn
Ochratoxin A	Wheat
Zearalenone	Corn

Any other commodities for which a manufacturer seeks test kit approval are referred to as “additional commodities.” AMS requires the use of naturally contaminated samples to evaluate test kit accuracy for the primary grain, but allows artificial fortification through the addition of standard solutions for additional commodity samples. A standard solution is a known amount of the mycotoxin dissolved in a solvent. AMS proposes to require that the extraction method used for the primary grain(s) be the same extraction method used for additional commodities. This change would provide evidence that the method can generate accurate results for both naturally contaminated grain and artificially contaminated commodities.

Update Criteria Issuance and Conformance

AMS proposes to issue the updated performance criteria within six months after the end of the comment period. Test kit submissions received more than one year after issuing the new criteria would be required to meet the new performance criteria to earn a certificate of conformance. During the transition year, manufacturers could choose to submit under the old or new criteria. However, certificates of conformance granted under the old performance criteria would expire after one year. In contrast, those granted under the new performance criteria would expire after three years. The expiration dates for existing certificates of conformance would not be affected.

Authority: 7 USC. 71–87k; 7 US C 1621–1627

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