In Iowa

Bounded on the north by the northern Iowa State line from the Big Sioux River east to U. S. Route 169; bounded on the east by U.S. Route 169 south to State Route 9; State Route 9 west to U.S. Route 169; U.S. Route 169 south to the northern Humboldt County line; the Humboldt County line east to State Route 17; State Route 17 south to C54; C54 east to U.S. Route 69; U.S. Route 69 south to the northern Hamilton County line; northern Hamilton County line east to Interstate 35; Interstate 35 northeast to C55; C55 east to S41; S41 north to State Route 3; State Route 3 to east U.S. Route 65; U.S. Route 65 north to C25; C25 east to S56; S56 north to C23; C23 east to T47; T47 south to C33; C33 east to T64; T64 north to B60; B60 east to U.S. Route 218; U.S. Route 218 north to Chickasaw County; the western Chickasaw County line; and the western and northern Howard County lines; bounded on the east by the eastern Howard and Chickasaw County lines; the eastern and southern Bremer County lines; V49 south to D38; D38 west to State Route 21; State Route 21 south to State Route 8; State Route 8 west to U.S. Route 63; U.S. Route 63 south to Interstate 80; Interstate 80 east to the Poweshiek County line; the eastern Poweshiek, Mahaska, Monroe, and Appanoose County lines; bounded on the south by the southern Appanoose, Wayne, Decatur, Ringgold, and Taylor County lines; bounded on the west by the western Taylor County line; the southern Montgomery County line west to State Route 48; State Route 48 north to M47; M47 north to the Montgomery County line; the northern Montgomery County line; the western Cass and Audubon County Lines; the northern Audubon County line east to U.S. Route 71; U.S. Route 71 north to the southern Sac and Ida County lines; the eastern Monona County line south to State Route 37; State Route 37 west to State Route 175; State Route 175 west to the Missouri River; and bounded on the west by the Missouri River north to the Big Sioux River; the Big Sioux River north to the northern Iowa State line.

In Minnesota

Yellow Medicine, Renville, Lincoln, Lyon, Redwood, Pipestone, Murray, Cottonwood, Rock, Nobles, Jackson, and Martin Counties.

In Nebraska

Cedar, Dakota, Dixon, Pierce (north of U.S. Route 20), and Thurston Counties.

In South Dakota

Bounded on the north by State Route 44 (U.S. 18) east to State Route 11; State Route 11 south to A54B; A54B east to the Big Sioux River; Bounded on the East by the Big Sioux River; and bounded on the south and west by the Missouri River. The following grain elevators are not part of this geographic area assignment and are assigned to Omaha Grain Inspection Service, Inc.: Scoular Elevator, Elliot, Montgomery County and two Scoular elevators, Griswold, Cass County, Iowa.

Authority: 7 U.S.C. 71–87k.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–24519 Filed 11–9–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–20–0061]

Mycotoxin Test Kit Design Specifications and Performance Criteria

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing its decisions regarding proposed changes to its mycotoxin test kit performance criteria after evaluating public comments received during prior publications in the **Federal Register** (85 FR 82427 and 86 FR 10531).

DATES: Applicable: November 10, 2022.

ADDRESSES: For access to the AMS mycotoxin test kit criteria, go to *https://www.ams.usda.gov/services/fgis/standardization/tke.*

FOR FURTHER INFORMATION CONTACT: Thomas A. Weber, Analytical Chemistry Branch Chief, Technology and Science Division, Federal Grain Inspection Service, AMS, USDA, 816–702–3811; Telephone: (816) 702–3811, or Email: *Thomas.A.Weber@usda.gov.*

SUPPLEMENTARY INFORMATION: Mycotoxins are toxic chemicals produced by certain fungal species under favorable environmental conditions. Many countries [1] 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 U.S.C. 71–87k), as amended, and the Agricultural Marketing Act of 1946 (7 U.S.C. 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 requested comments from test kit manufacturers and other stakeholders on proposed changes to AMS mycotoxin test kit criteria through a notice that was published in the **Federal Register** at 85 FR 82427 on December 18, 2020. The original 30-day comment period provided in the notice closed on January 19, 2021. Comments were received from ten stakeholders requesting an extension of the comment period. AMS reopened the comment period in the **Federal Register** at 86 FR 10531 on February 22, 2021, for 30 days to allow interested persons additional time to review and comment on the notice. The second comment period closed on March 24, 2021. A summary of the public comments, decisions, and future considerations follows.

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 and conform to AMS accuracy requirements. This range is referred to as the minimum range of conformance. AMS proposed to expand the minimum ranges for fumonisins, ochratoxin A, and zearalenone test kits to meet the current and anticipated future testing needs of the grain industry.

AMS proposed expanding the current minimum range for fumonisins from 0.50–30 parts per million (ppm) to 0.50–100 ppm to provide testing up to the U.S. Food and Drug Administration's highest industry guidance level in corn and corn products. Comments were received from eleven stakeholders. Four stakeholders endorsed this proposal, while two of the four supported the change for corn only. Three stakeholders were against the change, because the grain has no market value at such high levels or because of the difficulty in sourcing large quantities of contaminated grains with 100 ppm fumonisins. Six stakeholders were

[1] Worldwide regulations for mycotoxins in food and feed in 2003 [Online]. Food and Agriculture Organization of the United Nations, Rome, Italy, 2004. *https://www.fao.org/3/y5499e/y5499e00.htm* (accessed 5/24/2022).

against this change due to the risk for increased variation in the test results and suggested instead that narrowing the ranges would reduce variability. Five of these stakeholders recommended that the evaluation of test kits at the 100-ppm level should be optional. AMS believes that there may be limitations in test kit calibration linearity and additional sample preparation steps that could lead to increased variation. As a result, AMS will not implement proposed change at this time. AMS will follow up with test kit manufacturers to further assess the risk of increased variation and its impact.

To allow for expected testing variation below the maximum concentration levels of 5 parts per billion (ppb), required by a standard set by the Codex Alimentarius Commission, AMS proposed to expand the minimum range of concentrations for ochratoxin A from 5.0–100 ppb to 1.0–100 ppb. AMS was interested in comments on whether the maximum limit should also be lowered from 100 ppb to 20 ppb, resulting in a narrower minimum range (*i.e.,* 1.0–20 ppb). Comments were received from ten stakeholders. None of the stakeholders supported the AMS proposal to expand the minimum range. Five stakeholders asserted that the change would require test kits to be as accurate as the reference method, which they thought was an unreasonable expectation. However, no technical data was provided by the manufacturers to support that claim. Additionally, three stakeholders expressed concern that producing a 1.0 ppb ochratoxin A reference material may be difficult. However, five stakeholders supported an alternative lower concentration limit of 2–3 ppb and an upper limit of 20 ppb. AMS needs to gather and evaluate additional information from test kit manufacturers on their claim regarding the limitations of technology to quantify ochratoxin A at lower levels prior to setting a new limit. Therefore, AMS will not implement its proposed change at this time.

International regulators, including the European Union, have established maximum concentration levels for zearalenone at 100 ppb in cereals and other grains. To allow for expected testing variation below this regulatory limit, AMS proposed to expand the minimum range of concentrations from 100–1000 ppb to 20–1000 ppb. Comments were received from ten stakeholders. None of the stakeholders supported the AMS proposal. Five stakeholders supported changing the lower limit to 50 ppb, while two of the five also wanted an upper limit of 500 ppb. Four stakeholders requested that the required range of concentrations be narrower due to the potential for increased variability. AMS believes that there may be limitations in test kit calibration linearity and additional sample preparation steps that could lead to increased variation. As a result, AMS will not implement proposed change at this time. AMS will follow up with test kit manufacturers to further assess the risk of increased variation and its impact.

Evaluation of Mycotoxin Test Kit Accuracy

AMS proposed to change the way the acceptable ranges for test results are calculated to align with the Horwitz-Thompson equation, which is an internationally accepted benchmark for evaluating analytical method performance. Comments were received from fourteen stakeholders. None of the stakeholders supported the AMS proposal. Four stakeholders were against the proposal because of perceived limitations of applying the Horwitz-Thompson equation to immunochemistry-based methods. Four stakeholders stated that the proposed acceptable ranges would result in more complex and longer test procedures, leading to higher variation. Six stakeholders stated that increasing the precision in test kit results would be most effective by minimizing the variation introduced by sample preparation, which includes grinding to a smaller particle size, adjusting the sample size, and using uniform sample extraction procedures. Seven stakeholders stated that narrowing the required concentration ranges would result in more accurate test results. AMS believes that the Horwitz-Thompson model should be the benchmark for the evaluation of mycotoxin test kits, since countries importing U.S. grain worldwide utilize standardized mycotoxin testing methods with performance characteristics that conform to this model. Providing mycotoxin test kits that meet this benchmark would increase the confidence of importing countries in AMS testing services, thereby facilitating exports of U.S. grain. However, AMS recognizes the concerns expressed through the comments received and will not implement the proposed changes at this time in order to further investigate how to incorporate the Horwitz-Thompson model into the mycotoxin test kit criteria.

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. In effort to increase the robustness of the evaluation, AMS proposed to use three separate readers during the evaluation process. Three readers were chosen as a practical number, because three analysts are participating in the evaluation and each could use a separate reader for expediency. Comments were received from five stakeholders, and all supported the AMS proposal to use three separate readers during the evaluation process. AMS will implement this requirement in the mycotoxin test kit program to account for variability in readers.

Test Kit Manufacturer Analysts

AMS proposed to update the method performance criteria to allow up to two analysts from the test kit manufacturer to participate in the verification study conducted at the AMS laboratory. Comments were received from five stakeholders, all of whom supported this AMS proposal. AMS will implement this option in the mycotoxin test kit program to promote transparency in the verification process.

Extraction Method

AMS proposed that the extraction method used for the primary grain(s) should be the same as that used for additional commodities. This change would provide evidence that the method can generate accurate results for both naturally contaminated and artificially fortified grains and commodities. Comments were received from five stakeholders. None of the stakeholders supported the AMS proposal. Two stakeholders recommended that naturally contaminated samples be required in the evaluation of additional commodities. AMS recognizes that artificially fortified samples do not truly represent naturally contaminated samples, and therefore, not the most robust method for evaluating test kit performance. AMS has allowed for artificially fortified samples due to the lack of the natural occurrence of specific mycotoxins in particular commodities. Requiring the use of naturally contaminated samples is anticipated to reduce the number of additional grains and commodities for which AMS can provide testing services. AMS will not implement the proposed change at this time in order to further engage industry stakeholders on the impacts associated with continuing to allow the use of artificially fortified samples versus

requiring naturally contaminated samples in evaluating test kit performance.

Other Comments

Seven stakeholders made comments, which were beyond the scope of the changes proposed by AMS. These comments included recommendations to modify the minimum ranges of concentrations for aflatoxins and deoxynivalenol, to change the test kit certificate expiration period from three to five years, to revise the study design for the performance verification, to require all participants to use reference materials from one provider, and for AMS to provide guidance or recommendations on extraction procedures. AMS may engage stakeholders for further information about these recommendations and consider them in future program improvements.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–24520 Filed 11–9–22; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0030]

State University of New York College of Environmental Science and Forestry; Availability of a Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (Castanea dentata) Developed Using Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared a draft environmental impact statement (EIS) and draft plant pest risk assessment (PPRA) evaluating the potential environmental impacts and plant pest risk that may result from the approval of a petition for nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*) from the State University of New York College of Environmental Science and Forestry. The trees have been developed using genetic engineering to express an oxalate oxidase enzyme from wheat as a defense against the fungal pathogen *Cryphonectria parasitica,* making Darling 58 American chestnut tolerant to chestnut blight. We are making the draft EIS and draft PPRA available for public review and comment.

DATES: We will consider all comments that we receive on or before December 27, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2020–0030 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The petition and any comments we receive on this docket may be viewed at *Regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Subray Hegde, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1238; (301) 851–3901; email: *subray.hegde@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act, as amended (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Movement of Organisms Modified or Produced Through Genetic Engineering,'' regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the **Federal Register** on May 18, 2020 (85 FR 29790–29838, Docket No. APHIS–2018–0034),[1] revising 7 CFR part 340. However, this petition (APHIS Petition Number 19–309–01p) [2] for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020), which were effective at the time it was received by APHIS on January 21, 2020.

APHIS received a petition from the State University of New York College of Environmental Science and Forestry (ESF) seeking a determination of nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*). The petition states that Darling 58 American chestnut is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process [3] for soliciting public comment when considering petitions for determination of nonregulated status of regulated organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. On August 19, 2020, we announced in the **Federal Register** (85 FR 51008–51009, Docket No. APHIS–2020–0030) the availability of the blight-tolerant chestnut petition for public comment.[4] We solicited comments on the petition for 60 days to help us identify potential environmental and interrelated economic issues and impacts that APHIS should consider in evaluation of the petition. We received 4,320 comments on the petition from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, tribes, and unaffiliated individuals.

As part of our evaluation of the petition and consideration of public comments, APHIS concluded that the proposed determination of nonregulated status has the potential to significantly affect the quality of the human environment.[5] In a notice [6] published in the **Federal Register** on August 6, 2021

[1] To view the final rule, go to *www.regulations.gov* and enter APHIS–2018–0034 in the Search field.

[2] To view the petition, go to *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/petitions/petition-status.*

[3] On March 6, 2012, APHIS published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to *www.regulations.gov* and enter APHIS–2011–0129 in the Search field.

[4] To view the notice, supporting documents, and the comments that we received, go to *www.regulations.gov* and enter APHIS–2020–0030 in the Search field.

[5] Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment. Impacts/effects include ecological (such as effects on natural resources, and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects (see 40 CFR 1508.1).

[6] To view the notice and the comments we received, go to *www.regulations.gov* and enter APHIS–2020–0030 in the Search field.