



National Seed Health System

TITLE: Technical Panel Procedures and Criteria for the Evaluation of Laboratory Seed Health Testing Methods for the NSHS

VERSION: 3.0

DATE: 01/22/2019

Reference Manual A-Section 3.1

3.1 TECHNICAL PANEL PROCEDURES AND CRITERIA FOR THE EVALUATION OF LABORATORY SEED HEALTH TESTING METHODS FOR THE NSHS

This document replaces “Technical panel peer review procedure for laboratory seed health Reference Methods” Version: 1.1, Date: 04.01.2016

3.1.1 Introduction:

The National Seed Health System (NSHS) has developed a peer review system to evaluate and approve seed health test methods to be used for phytosanitary certification.

Seed health testing methods may be proposed by NSHS-accredited entities, the NSHS Administration Unit (AU) at Iowa State University, or other stakeholders in phytosanitary certification of seeds for export. Methods should be submitted using the NSHS method template available on the NSHS website, www.seedhealth.org. Proposed methods should meet the criteria described in [Appendix 1, “Development and Validation Data Targets for Proposed NSHS Seed Health Testing Methods”](#), and should be submitted to the AU with supporting data as described in Appendix 1.

The peer review system consists of establishing a Technical Panel of 3-4 international experts that evaluates the proposed seed health test method(s) and the supporting method validation data for specific host-pathogen combinations. Technical Panel members have expertise in pathogens of the assigned crop. They are drawn from academia, government, and the seed industry.

The following criteria are to be used by the Technical Panels to evaluate seed health testing methods. Based on the results of the Technical Panel evaluations, the NSHS Administration Unit (AU) will make a recommendation to the NSHS Policies and Procedures Board (PPAB) regarding the approval of methods for use by NSHS-accredited entities.

The target timeline for this procedure from method submission to PPAB approval is 120 days.

3.1.2 Criteria for Evaluation of Proposed Methods

3.1.2.1 **Sample Size:**

Methods should specify a minimum sample size. Appropriate sample size will differ among crop seeds and pathogens. Panel members will use their expertise and judgement to assess whether the proposed sample size is appropriate, based on available knowledge of seed transmission risk, the biology of the pathogen and threshold for outbreaks (if it is known). Sample sizes larger than the minimum may sometimes be required to meet import requirements.

3.1.2.2 **Sensitivity:**

Methods should be supported by data demonstrating the sensitivity of the assay in terms of the percentage of contaminated seed or target pathogen quantification, such as CFU, number of conidia, etc.

Appropriate sensitivity levels will differ among crop seeds and pathogens. Panel members will use their expertise and judgement to evaluate whether the method in question is adequately sensitive.

3.1.2.3 **Specificity:**

Methods should be supported by data demonstrating the specificity of the assay, including results from a range of isolates of the pathogen from different origins. This may include different hosts, geographical regions, or different pathogen races, as appropriate. Data also should be provided that demonstrate that the method can distinguish the target pathogen from closely related organisms.

3.1.2.4 **Selectivity:**

Methods should be supported by data demonstrating the ability of the method to detect the target pathogen(s) without being affected by seed matrix variations. Methods should be evaluated using contaminated samples of seeds of different origins.

3.1.2.5 **Repeatability:**

Methods should be supported by data demonstrating that the method produces repeatable results. This can be demonstrated through replicated testing of well characterized samples over the course of several method runs within the same lab.

3.1.2.6 **Reproducibility:**

Methods should be supported by data demonstrating that the method produces results that are reproducible. This can be demonstrated through testing of well characterized samples by multiple labs.

3.1.2.7 **Robustness:**

Methods should be supported by data demonstrating that the method is reliable with minor variations in method parameters. This can be demonstrated by multi-lab testing and/or systematic variations in method parameters.

Comparison with Existing Methods. If there is an established NSHS method for the host/pathogen combination in question, data should include a comparison of results between the proposed and established method. To be approved, a proposed method should perform better than the established method, or offer advantages in terms of efficiency, cost, or ease of use. This information can be generated internally through the developmental process or through a comparative evaluation of methods across labs.

Historical Data. If a method has been routinely used in industry or academia, available data on frequency of use, and effectiveness is valuable. There may also be a record of the number of complaints associated with a particular assay under consideration if it has previously been used commercially. These records may be a good indicator of the effectiveness of the assay and it is encouraged that these data be provided in the data submission package.

Other Criteria. Panel members may consider other criteria, which might have significant impact on the recommendation for use of a method. These may include cost, equipment or facilities required, time to obtain results, or other practical aspects of method implementation.

3.1.3 Evaluation Procedure

3.1.3.1 Administration Unit Responsibilities

- 3.1.3.1.1 The NSHS AU will consult with method developers as needed to clarify method format and data expectations prior to and after submission of methods and supporting data. Clarification of method protocols and supporting data may require revisions by the method developer after submission. The AU will request such revisions as early as possible after submission.
- 3.1.3.1.2 In consultation with method developers and other stakeholders, the AU will make a determination whether the method is eligible to be considered as a Temporary Standard. For method developers, please note that this is an exception process and will not be exercised frequently.
- 3.1.3.1.3 The NSHS AU will develop a technical package of scientific information on each host/pathogen combination and available data on the proposed seed health testing method(s). This will be accomplished by summarizing information provided by the submitter of the method (if applicable), conducting a literature review of the pathogen, and contacting seed scientists to obtain information on:
 - Relevant data on seedborne and seed transmission aspects of the pathogen

- Existing seed health test methods
 - Validation data included with the proposed method
 - Other validation data available from ISHI, ISTA, or other sources
- 3.1.3.1.4 The AU shall identify scientists with relevant expertise to serve on ad hoc Technical Panels to review each proposed method or methods for a host-pathogen combination. Best efforts will be made to assemble Technical Panels from diverse institutions and companies, including individuals without conflicts of interest regarding the proposed method(s).
This step will be done concurrently with step 3.1.3.1.3
- 3.1.3.1.5 The AU shall forward to each panel member a detailed protocol for each proposed laboratory seed health testing method. Included with the protocol will be all relevant scientific documentation of validation results or results from routine use. The AU and panel members will negotiate a mutually acceptable deadline for completion of the review.
- 3.1.3.1.6 The AU will inform panel members whether the method is eligible to be considered as a Temporary Standard.
- 3.1.3.1.7 The AU receives NSHS TECHNICAL PANEL REVIEW - Individual Report Form from Technical Panel members.
- 3.1.3.1.8 The AU evaluates the individual reports from all Technical Panel members and prepares a Summary Technical Report, which includes a recommendation for disposition of test methods and the scientific basis for the recommendation. The recommendation should be made on the “NSHS TECHNICAL PANEL REVIEW - Summary Report Form”.
- 3.1.3.1.9 The AU submits the Summary Technical Panel Report and recommendation to the Policies and Procedures Advisory Board (PPAB) of NSHS for final approval.
- 3.1.3.1.10 The AU is responsible for ensuring that methods that are adopted as Temporary Standards are transitioned to a full standard method status or are removed from the accredited method list within the time frame allowable for Temporary Standard methods.

3.1.4 Technical Panel Responsibilities

- 3.1.4.1 It will be the responsibility of panel members to evaluate seed health test methods included in the technical package based upon the criteria described in Appendix 1.

3.1.4.2 Each Technical Panel member shall prepare a report on the form titled “NSHS TECHNICAL PANEL REVIEW - Individual Report Form” rating each of the methods evaluated by these criteria. He or she then should state their justification for their rating, and if needed, make recommendations for revisions to the method or for further data collection that may be needed.

The panel members should use the following rating system to make a recommendation for each method.

- Class A. Standard Method: the method is acceptable as a standard method and should be added to the list of NSHS-approved methods (following approval by the NSHS PPAB).
- Class B. Temporary Standard Method: the method meets an immediate testing need, but requires revision or additional validation data before acceptance as a standard method. Temporary Standards may be added to the list of NSHS-approved methods for a period of 24 months from the time of the approval by the NSHS PPAB. After 24 months, temporary standards must be re-reviewed on the basis of revisions or new data. If no revisions or new data are available, the method is removed from the list. This option is only available if the Technical Panel was informed a priori by the AU that the method is eligible for Temporary Standard status.
- Class C. The method should not be accepted. A recommendation may be made for improvements to the method, which can be re-reviewed at a later time.

3.1.4.3 Panel members then return their individual report to the AU.

3.1.5 Policy and Procedures Advisory Board Responsibilities

3.1.5.1 The NSHS PPAB reviews the Summary Technical Panel Report and its recommendation, discusses any concerns, and conducts a vote to approve the method at the A level (Standard Method) or reject the method (C level) based on the Technical Panel reports and AU recommendation.

3.1.5.2 In cases of an immediate testing need, the NSHS PPAB may vote and accept a method as a temporary standard (Class B).