



Principles and Conditions for Laboratory Accreditation under the Performance Based Approach

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ECOM	HOAT GMO COMMITTEE	ECOM

SCOPE

The scope of this document is to specify principles, conditions and requirements for laboratory accreditation for methods not standardised in the ISTA International Rules for Seed Testing but considered to fall under the category of 'performance approved methods' in accordance with Chapter 19 of the ISTA Rules.

RELATED DOCUMENTS

ISTA Accreditation Standard for Seed Testing and Seed Sampling

ISTA International Rules for Seed Testing

Performance Data Evaluation Document(s)

The ISTA Proficiency Test Programme

RESPONSIBILITIES

n.a

PERFORMANCE APPROVAL OF METHODS

Under the Performance Based Approach, a laboratory may develop and/or use a method not published in the International Rules for Seed Testing and apply for ISTA Accreditation to cover this method once the laboratory formally approves the method on the basis of performance data.

SCOPE OF ACCREDITATION

Performance approved methods to be included in a laboratory's scope of ISTA Accreditation must be defined in terms of the method used, the species tested and the specified trait that is to be determined.

ACCREDITATION PROCESS

GENERAL CONDITIONS

- The ISTA Accreditation Standard for Seed Testing and Seed Sampling constitutes the reference document specifying the criteria which must be fulfilled by laboratories to qualify for ISTA Accreditation.
- Evaluation of technical competence includes data from proficiency test participation and performance approval of test methods.
- Accreditation can only be granted for performance approved methods evaluated in accordance with relevant performance data evaluation documents.

AUDIT PROCESS

Proficiency test participation

Relevant results from proficiency test participation will be taken into consideration for assessing technical competence. Continuing participation in the ISTA GMO Proficiency test programme and satisfactory performance in relevant proficiency tests is a prerequisite for attaining or maintaining the status as an accredited laboratory. Laboratories shall use the method for which they are accredited where applicable. A second set of results based on protocols not included in the scope of accreditation may be submitted at the laboratory's discretion. The rating will refer to the accredited test.

Document evaluation

Part of the document review, usually prior to the on-site assessment is an evaluation of performance data for each combination of species, test method and trait.

For some combinations of species, method and trait, a performance data evaluation as described in the relevant ISTA documents will have to be performed, while for other combinations, suitable alternative performance data may be used. There must be at minimum one set of performance data in accordance with the given protocol per species and methodology (e.g. PCR, ELISA, bioassay). For other traits on the same species applying the same methodology, alternative data may be provided.

In case of group testing (sub-sampling) qualitative performance data are requested and evidence has to be provided that the background in statistical evaluation is sufficient to set up appropriate testing plans, to evaluate the results, and to report them on an ISTA certificate.

On-site assessment

During the on-site assessment the audit team will assess whether implementation aspects are appropriately addressed and whether practice complies with the documented procedures. To that effect, training, equipment management, facilities, reporting and running the overall quality managements system will be assessed.

A complete practical demonstration of any performance approved method will not be required.

CHANGES TO THE SCOPE OF ACCREDITATION

Changes in a method covered by ISTA Accreditation must be reflected in the laboratory's scope of accreditation and, if justified by the nature of the changes, may require a full assessment of the latest performance data records for the changed method, and other relevant aspects.

DISTRIBUTION LIST

Published at the ISTA website

REVISION HISTORY

Version #	Changes
3.0	Layout change Full revision