



INTERNATIONAL SEED TESTING ASSOCIATION

APPROVED BY THE EXECUTIVE COMMITTEE OF ISTA
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POSITION PAPER

ON

ISTA'S STRATEGY REGARDING METHODS FOR THE DETECTION, IDENTIFICATION AND QUANTIFICATION OF GENETICALLY MODIFIED SEEDS IN CONVENTIONAL SEED LOTS

1. The Vision

ISTA seed testing laboratories are competence centres for varietal purity testing of GM varieties as well as for the detection, identification and quantification of GM seeds in conventional seed lots and provide uniform test results all over the world.

2. The Present Situation

The adventitious presence of GM seeds in non GM seed lots has increasingly become a problem for the international seed trade. Several cases with sometimes tremendous consequences for the trading companies have come to awareness of the public.

Besides the politically difficult discussions regarding the threshold for GM seeds in conventional seed lots, the establishment of relevant, reliable and economical methodology for detection, identification and quantification of GMO content (in the following called GMO testing) in conventional seed lots continues to be a challenge.

Quite a number of research institutes, inspection agencies and companies all over the world are developing different strategies and methods for GMO testing. Furthermore, the technology for GMO testing is evolving rapidly. The advantages and disadvantages of all methods in the market today are under an intensive and critical discussion. At the moment the accuracy and reproducibility of test results seem to be more important for the international trade than the question by which method these results are obtained. Without an appropriate reproducibility of GMO testing between laboratories all over the world, the risk for the seed industry to ship seed is high.

Methods using PCR technology seem to be very powerful for this area but difficult in their application and expensive in the traditional seed testing context.

There is already a broad range of PCR based methods in routine use. The quality of these test results depends more on the methodology and on the equipment used than in all other classical seed testing methods. This makes a standardisation of this methodology on an international scale very difficult.

3. ISTA's Strategy

In view of the present situation, and as a result of continuously reviewing the developments and discussions in this area, ISTA has updated its position as laid in the paper of February 2001 and has established the following strategy:

ISTA will focus its activity on developing a system targeting the uniformity in GMO testing results, not only by the uniformity in GMO testing methodology, but by a performance based approach. For realisation of this approach the ISTA GMO Technical Committee will be active in the following directions:

- An ISTA Rules Chapter for the detection, identification and quantification of GMO in conventional seed lots will be established. This chapter will not contain specific methods, but will define a level of reproducibility required to report test results on an ISTA International Seed Lot Certificate.
- The ISTA GMO Technical Committee will organise proficiency tests on GMO testing in conventional seed.
- The ISTA GMO Technical Committee will set up a platform for the exchange of information between laboratories.

In the performance based approach, the laboratories have to demonstrate that the GMO detection, identification or quantification methods used for reporting results on the ISTA International Seed Lot Certificate fulfil requirements concerning repeatability and reproducibility. This can be done using certified reference materials and/or using results of proficiency tests. The ISTA GMO Technical Committee will set up acceptance criteria for proficiency performance and its documentation.

In order to support the laboratories, the ISTA GMO Technical Committee will offer proficiency tests to all interested ISTA seed testing laboratories. Participation in the proficiency test system will be a requirement for reporting results of GMO on an ISTA International Seed Lot Certificate.

The experimental error of GMO testing shall be estimated from the data of these proficiency tests when an acceptable level of reproducibility is achieved.

With this strategy, ISTA's intention is to improve the reliability of and the confidence in GMO testing results in international trade.

4. ISTA's Action Plan

4.1. GMO Testing Chapter in the ISTA Rules

The activities of the ISTA GMO Technical Committee will concentrate on the establishment of a new chapter on GMO testing in the ISTA Rules. This chapter will have a specific direction in view of all the different methods presently in routine use and not transferable from one laboratory to another without high degree of diligence in following protocols exactly. Deviating from the classical direction followed in the ISTA Rules, this chapter will not primarily standardise the procedure of a specific method. The aim is to define the accuracy and precision during the whole process from sampling up to reporting so that the final test result reported on the ISTA International Seed Lot Certificate has a documented reliability. The test method itself is only one component in this process. The chapter will be open for different methods such as bioassays, protein based methods and DNA based methods.

Since not only test results will be expected by the applicant on the ISTA International Seed Lot Certificate but also information on the compliance with thresholds, careful considerations on how to report GMO testing results are required.

4.2. Proficiency Tests

Only qualitative tests should be performed in the beginning, focusing on the question: Can the presence of GM seeds in a non GM sample be detected reproducibly?

Two test rounds shall be performed each year. In the first round of the proficiency test, ISTA will focus on corn (*Zea mays* L.), with seed being used as testing material. The choice of testing method will be left to the laboratory.

4.3. Platform for Exchange of Information

An information platform will be established on the ISTA website. Information will be provided about:

- the ISTA laboratories involved,
- activities within ISTA,
- equipment suppliers,
- links to websites and databases,
- programs for primer design,
- progress in international standards,
- etc.

For communication the ISTA web board should be used.

Training will be offered in workshops and seminars.

The presented approach is a new strategy for ISTA and needs careful consideration and discussion. Therefore, the ISTA GMO Technical Committee will be supported in its activities by other ISTA Technical Committees as STA and BSC as well as by the Secretariat. It shall maintain contacts with other organisations active in this area. Furthermore, the ISTA GMO Technical Committee will keep close contact with the ISTA Executive Committee via the ISTA Secretariat to ensure the successful development of this strategic approach and acceptable practical solutions for a recognised contribution of ISTA in this area.