Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Annex

Facilities testing for genetically modified organisms (GMO)

July 2018

Table of Contents

Facilities testing for genetically modified organisms (GMO)

This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting testing for genetically modified (GM) material.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by their scope of accreditation (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO/IEC 17025 but since not all clauses require interpretation the numbering may not be consecutive.

Testing for genetically modified sequences in foodstuffs or whole grain and related plant materials relies on the ability to test for the specific DNA sequences associated with modifications and/or the promoting and terminating sequences associated with the inserted sequences.

Accreditation covers qualitative and quantitative analysis of GM material through the use of DNA extraction and Polymerase Chain Reaction (PCR) methods.

In recognition of the continual development of new GM materials, NATA operates a flexible scope policy. When a facility has developed the capacity to detect a new GM event or construct, this will be added to the scope of accreditation without the need for supporting documentation to be submitted to NATA where the analysis is undertaken using the same technique that is covered by the scope of accreditation. Where a new technique is implemented that has not been assessed an variation visit will be required.

The competence of a facility to develop and implement tests for new GM events and constructs will be ascertained at the initial assessment or the first assessment that such testing is requested to be added to the scope of accreditation. At reassessments, a sample of GM events or constructs added since the last assessment will be reviewed.

6 Resource requirements

6.3 Facilities and environmental conditions

6.3.1 In order to reduce the risk of false positive results from cross-contamination or carry-over contamination of samples and reagents by other samples in the laboratory or by amplified material, four physically separate and contained areas with known air conditioning/ventilation airflows are required within a facility undertaking nucleic acid amplification for the detection of GM materials. The four work areas are:

- sample preparation;
- DNA extraction;
- reagent preparation;
- product analysis.

6.4 Equipment

6.4.10 Specialised equipment (i.e. thermocycler, nucleic acid analyser, spectrophotometer) is required for detection of labelled DNA fragments. Many instruments have internal diagnostic checks built into them and, as a minimum, the recommendations from manufacturers should be followed.

6.5 Metrological traceability

6.5.1 Reference materials used as controls in the validation of new assays and as routine controls must comply with the requirements of the *General Accreditation Criteria: Metrological Traceability.*

7 Process Requirements

7.2 Selection, verification and validation of method

7.2.1.1 The following reference documents covering nucleic acid testing should be consulted:

- Former Subcommittee of Animal Health Laboratory Standards (SCAHLS) Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques
- National Pathology Accreditation Advisory Council Laboratory, Requirements for medical testing of human nucleic acids

7.2.2.1 Where possible consideration should be given to grouping like matrices to reduce the volume of work required to undertake validation.

Note: See the FSANZ website at www.foodstandards.gov.au information on the currently approved/pending GM events.

7.4 Handling of test or calibration items

7.4.1 The high sensitivity of methods dictates a higher than usual awareness to the possibility of cross-contamination during transport, storage, preparation and analysis. (See 6.3.1 Accommodation.)

7.7 Assuring the validity of results

7.7.1 Controls that are incorporated with the GMO test system must address inhibition, sensitivity and contamination.

7.8 Reporting of results

7.8.1 General

7.8.1.2 Reporting the results of GM material detection must be sufficiently descriptive to allow the reader a clear understanding of what tests have been conducted and to what level of detection.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the general requirements of ISO/IEC 17025, a test report for GM material testing must also include information on the limitations of the particular detection method used for the particular sample or sample type.

The content of test reports is influenced by the nature of the matrix tested. For unprocessed materials such as soya beans, canola seeds or lupin seeds, it is important to indicate the amount of sample or the number of seeds ground prior to DNA extraction.

Where highly processed materials are tested, it is possible that an insufficient quantity of DNA may be extracted to allow the presence of GM material to be detected. In such cases a null result can be reported. Facilities should discuss the possibility of a null result with customers prior to testing if the matrix submitted is highly processed.

7.8.7 Reporting opinions and interpretations

7.8.7.2 No affirmation shall be made stating that there is no GM material present in the sample analysed as determined from test samples.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

NATA Publications

NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by the facility's scope of accreditation

General Accreditation Criteria Metrological Traceability

Other Publications

Former Subcommittee of Animal Health Laboratory Standards (SCAHLS) *Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques*

National Pathology Accreditation Advisory Council Laboratory, *Requirements for medical testing of human nucleic acids*

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Whole document	Clauses have been aligned with ISO/IEC 17025:2017. No new interpretative criteria or recommendations have been included.