Biological Testing ISO/IEC 17025 Application Document

Annex D: Accreditation of facilities testing for genetically modified organisms (GMO)

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This document provides additional interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting testing for GMO.

Applicant and accredited facilities must also comply with the ISO/IEC 17025 standard and the Biological Testing field application document and any field annexes, policies and/or technical circulars (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 GMOs through the use of DNA extraction and Polymerase Chain Reaction (PCR) methods of detection.

Protein testing methods for detecting GMOs are not covered in this document as they are still under development.

5.2.1 Staff qualifications and experience

Staff approved to release results must be able to evaluate and interpret test results and have the ability to communicate orally the technical aspects and regulatory requirements of GMO testing to a lay audience.

5.3 Accommodation and environmental conditions

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 GMO. The four work areas are:

- Sample preparation
- DNA extraction
- Reagent preparation
- Product analysis

5.4 Test and calibration methods and method validation

Guidelines available on testing for GMO testing facilities covers some general and DNA/PCR specific issues relating to method documentation and relevant quality control.

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

- Subcommittee of Animal Health Laboratory Standards (SCAHLS) *Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques*
- National Pathology Accreditation Advisory Council *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis*.

5.4.5 Method validation

Methods must be validated for each group of products to establish the method's applicability and limitations. The range of matrices that require individual validation includes natural and processed materials that are likely to present individual challenges to the general method.

Records of validation work must cover the entire range of products for which accreditation is sought.

See the FSANZ website at www.fsanz.gov.au for information on the currently approved/pending/non-approved GM crops.

5.5 Equipment

Specialised equipment (i.e. thermocycler, nucleic acid analyser, spectrophotometer, enzyme immunoassay microtitre plate, fluorometer, luminometer, microscope and ELISA plate reader) is required for detection of labeled DNA fragments. Many instruments have internal diagnostic checks built into them and, as a minimum, the recommendations from manufacturers should be followed.

5.8 Handling of test and calibration items

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

5.9 Assuring the quality of test and calibration results

A quality control program that covers staff proficiency, infrequently performed matrices and performance in external proficiency testing programs, where available, is expected to be followed with appropriate analysis of data and corrective actions.

Controls that are incorporated with the GMO test system must address inhibition, sensitivity and contamination. The quality of critical reagents must be tested to ensure their optimal performance prior to the use in routine testing.

5.10 Reporting of results

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

In addition to the general requirements of ISO/IEC 17025, a test report for GMO testing must also include information on:

- sample size;

- method of preparation; and
- limitations of the particular detection method used for the particular sample or sample type.

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

Examples of negative and positive test reports are provided in the guidelines used for the assessment of facilities testing for GMO available from the NATA website.