MOSTI

STANDARDS MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

SPECIFIC TECHNICAL REQUIREMENTS 1.5 (STR 1.5)

SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF LABORATORY TESTING FOR GENETICALLY MODIFIED ORGANISMS (GMO)

Issue 2, 31 January 2007
(Supplementary to MS ISO/IEC 17025)

STANDARDS MALAYSIA ACCREDITED LABORATORY

MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia (STANDARDS MALAYSIA)

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TECHNICAL REQUIREMENTS

CLAUSE 5

NOTE: Clause numbers correspond to those in the standard MS ISO/IEC 17025

5 TECHNICAL REQUIREMENTS

5.1 Introduction & Scope

This document shall be read in conjunction with MS ISO/IEC 17025 and other specific criteria published by Department of Standards Malaysia (STANDARDS MALAYSIA).

The purpose of this document is to establish specific criteria for accreditation of laboratories involved in testing for genetically modified organism (GMO) under the Laboratory Accreditation Scheme of Malaysia. Analysis for the detection and quantification of GMO covers both DNA and protein based methods.

DNA based Method

The most common procedure for DNA-based detection is Polymerase Chain Reaction (PCR), which detects specific sequence(s) within the introduced DNA. This technique is sensitive, specific and generally unaffected by most food processing techniques. It is a reliable qualitative and quantitative method for the detection of the GMO.

Protein based Method

The GMO may be identified by detection of the expressed novel protein encoded by the introduced DNA. Protein based analysis is routinely performed using the Enzyme Linked Immunosorbant Assay (ELISA), which uses specific antibodies or an immobilized antibody detection technology. Protein based method also provides reliable qualitative and quantitative assessment for the detection of the GMO.

5.2 Personnel

The testing laboratory shall have sufficient personnel having appropriate technical knowledge and proficiency to carry out the experiments and analysis. The signatory(ies) shall be knowledgeable in the scope of work sought or accredited.

- The signatory shall possess at least a Bachelor of Science degree in an appropriate science field such as Molecular Biology, Chemistry, Biochemistry, Microbiology, Genetics or Biotechnology related field and at least one year working experience in GMO analytical laboratory.
- Laboratory assistant/technologist shall have at least a SPM certificate.

5.3 Accommodation and environment conditions

GMO testing laboratory

The laboratory should have dedicated areas for handling raw samples, processed samples, PCR/protein set-up and post analysis to minimize cross-contamination. The GMO testing laboratory should also be flexible in meeting increased sample volumes, process changes and new technologies.

Where possible, specific equipment and facilities should be dedicated for GMO analysis and not used for other purposes/analysis.

5.4 Test methods and method validation

Laboratory may use methods developed by the International Organisation for Standardisation (ISO), CODEX, Malaysian Standard, Journals, European Committee for Standardization (CEN) or any appropriate in-house methods. In all cases, the laboratory shall ensure that each

particular method is adequately validated for its intended purpose. Documentation shall refer to the method source and acknowledge any modifications and/or additions. Standard methods do not require validation other than establishing the performance characteristic of the method to the products under test and establishing staff competence in the method (verification process). All methods shall be applicable to the material specified in their scopes.

Method validation / performance

Two approaches may be used;

i. Method approach, which constitutes the whole chain from extraction up to the PCR/protein method.
ii. Modular approach, whereby the different method parts (e.g. extraction protocol and PCR/protein method) can be considered separately.

Applicability and limitations of the validated method for each defined group of products shall be established. Performance criteria, recommended by national/international organization, which are suitable for the intended purpose shall be established.

Validation of a Qualitative/Quantitative PCR Method

Qualitative/quantitative PCR methods shall be validated for its intended purpose. Validation should be conducted according to the harmonized ISO/IUPAC/AOAC/CEN protocols.

Validation of a Qualitative/Quantitative Protein-Based Method

Qualitative/quantitative protein-based methods shall also be validated for its intended purpose. Validation should be conducted according to the harmonized ISO/IUPAC/AOAC/CEN protocols.

Measurement uncertainty

Laboratories performing quantitative analysis should estimate measurement of uncertainty according to guidelines established by CODEX.

5.5 Equipment

As in the standard MS ISO/IEC 17025.

5.6 Measurement traceability

All equipment used for test shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of equipment.

Reference Standards and Reference Materials

The laboratory concerned shall have a reference standard for detecting any particular GMO. The reference standard shall be obtained from a recognized organization such as Institute of Reference Material and Measurement (IRMM) and Nippon Gene. Appropriate record on the reference standard such as date of receipt, arrival condition and appropriate test condition shall be maintained. The stability of the reference material under storage and test conditions shall be known.

5.7 Sampling

The general requirement for sampling shall closely follow the MS ISO/IEC 17025 document. Wherever possible, specific instructions of the CODEX product committees and/or other relevant internationally recognized sampling standards should be met.

5.8 Handling of test and calibration items

In order to prevent cross-contamination, there should be separate rooms and/or areas for storing test and reference materials. Where possible, the flow should be in one-flow direction in order to minimize and prevent any chances of cross-contamination.

5.9 Assuring the quality of test and calibration results

Quality control measures shall include positive and negative controls (template free control), and extraction blank for every batch of analysis. The laboratory shall participate in relevant Proficiency Testing program.

5.10 Reporting the results

In addition to what is required by MS ISO/IEC 17025, the test report for GMO testing should also include information on:

i. The GMOs tested
ii. Limit of detection for qualitative analysis
iii. Limit of detection and limit of quantification for quantitative analysis

Acknowledgements

1.	En. Tham Kok Pheng (Chairman)	STANDARDS MALAYSIA
2.	Pn. Fariza Wan Abdullah (Secretary)	STANDARDS MALAYSIA
3.	En. Ahmad Latfi Mahamud	Jabatan Kimia Malaysia, Petaling Jaya
4.	Prof. Dr. Son Radu	Universiti Putra Malaysia (UPM)
5.	Assoc. Prof. Dr. Ismanizan bin Ismail	Universiti Kebangsaan Malaysia (UKM)
6.	Dr. Zamri Ishak	Pusat Penyelidikan Bioteknologi (MARDI)
7.	En. Rajinder Singh	Lembaga Minyak Sawit Malaysia (MPOB)