PIT-GMO-ALGMOT

Approval of Laboratories for Genetically Modified Organism Testing

MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry
P O Box 2526
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New Zealand

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ENDORSEMENT

This MAF Biosecurity New Zealand standard is hereby approved

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Dr Stephen Butcher
Plant Imports & Exports Group Manager
Date:

REVIEW

This MAF Biosecurity New Zealand (MAFBNZ) standard is subject to review and amendment at any time, to ensure that it continues to meet current needs. Amendments will be made to the signed original as required.

Interested parties are advised to consult the MAF website to obtain the most up to date copy of this standard.
http://www.biosecurity.govt.nz/regs/imports/plants/gmo#labs

AMENDMENT RECORD

Amendments to this standard will be given a consecutive number and will be dated.

Amendment No:	Entered by:	Details:	Date:
1	KHurr	Requirement for laboratory accreditation to ISO/IEC 17025: latest version	14 February 2005
2	KHurr	Updated organisational & contact details	10 September 2007
3	KHurr	Updated Testing protocol references	2010
4			
5			

SIGNED ORIGINAL

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Plant and Plant Product Imports

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CONTACT PERSON

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1. INTRODUCTION

1.1 SCOPE

This standard describes the requirements for the approval of laboratories used for testing plant material (e.g. seed for sowing) for the presence of genetically modified organisms (GMOs). It also specifies how these laboratories and their operators may be approved.

Consignments of plant material may be tested either prior to export or upon arrival in New Zealand by a MAF-approved laboratory.
Before plant material can be imported into New Zealand, an import health standard for the commodity concerned is also required.

1.2 REFERENCES AND COMPLEMENTARY DOCUMENTS

The following documents are referred to, or complement the implementation of this standard:

- The Biosecurity Act, 1993
- The Hazardous Substances and New Organisms Act (HSNO) 1996, and subsequent amendments
- Import health standards issued by MAF Biosecurity New Zealand.
- Permits to Import issued by MAF Biosecurity New Zealand.
- MAF Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed
- MAF standard 152.04.03F "Requirements for Holding and Processing Facilities (Class: Transitional Facilities) for Uncleared Risk Goods.
- ISO/IEC 17025 (latest version): *General requirements for the competence of testing and calibration laboratories*.

1.3 DEFINITIONS AND ACRONYMS

For the purposes of this MAFBNZ standard the following definitions and acronyms apply:

Accreditation

A process for ensuring that the supplier has the capacity and the technical competence to provide test results in accordance with the requirements specified by the standard ISO/IEC 17025.

Accredited

Official recognition by an approved accreditation provider that a laboratory is competent to provide a service in accordance with the standard ISO/IEC 17025.

Approval

Written approval received from the Plant Imports and Exports Group Manager, MAF Biosecurity New Zealand (MAFBNZ), to operate as a GMO testing laboratory.

Audit

An official evaluation to determine the degree of conformity with prescribed criteria in a specified standard.

Competence

The ability to do something well and effectively.

Compliance

Operation of a testing laboratory according to the requirements of this standard.

Consignment[1]

A quantity of plants, plant products and/or other regulated articles being moved from one country to another and covered by a single phytosanitary certificate (a consignment may be composed of one or more lots).

Director-General

Chief executive of the Ministry of Agriculture and Forestry.

DNA

Acronym for Deoxyribonucleic Acid, the genetic material of a cell.

Genetically modified organism (GMO)

Unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material have been modified by *in vitro* techniques or are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques. Section 2, Hazardous Substances and New Organisms Act (HSNO) 1996.

Import health standard

A document issued under section 22 of the Biosecurity Act (1993) that specifies the requirements for the effective management of risks associated with the importation of risk goods into New Zealand.

International Electrotechnical Commission (IEC)

A global organisation that promotes the development of standardisation in relation to electrical, electronic and related technologies.

International Standardisation Organisation (ISO)

A worldwide federation of national non-governmental standard bodies established to promote the development of standardisation and related activities.

Limit of Detection (LOD)

The limit of the analytical method in detecting the presence of a genetically modified organism in the sample.

Limit of Quantitation (LOQ)

The limit of the analytical method in quantifying the amount of genetically modified DNA present in the sample.

MAF BNZ

Acronym for Ministry of Agriculture and Forestry Biosecurity New Zealand

Non-compliance

An incidence where the requirements of a specification, contract, regulation or standard are not met.

Operator

The person who has overall responsibility for the testing laboratory, its maintenance and operation.

Polymerase Chain Reaction (PCR)

A method which selectively amplifies a defined section of an original DNA template, using a DNA copying enzyme, to create many thousands of DNA copies which can then be detected.

Procedure

A document that specifies, as applicable, the purpose and scope of an activity; what shall be done and by whom; when, where, and how it shall be done; what materials, equipment, and documentation shall be used; and how it shall be controlled.

Standard[1]

Document established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [FAO, 1995; ISO/IEC Guide 2:1991 definition].

Testing

Official examination to determine if a genetically modified organism is present in a seed line.

Testing laboratory

Laboratory approved by MAF Biosecurity New Zealand to carry out testing to determine if a genetically modified organism is present or to identify the genetically modified organism.

Validated methods

Methods which have been tested on a range of samples in intra- and inter-laboratory trials and found to give consistently reliable results.

[1]As defined by the FAO Glossary of Phytosanitary Terms
[2]As defined by the Hazardous Substances and New Organisms Act, 1996

2. SERVICE AND SYSTEM REQUIREMENTS

2.1 TESTING LABORATORY

2.1.1 The testing laboratory must be constructed and operated in a manner that reduces the possibility of cross-contamination of samples during receipt and processing.

2.1.2 The testing laboratory shall be secured so that material cannot be contaminated, mixed or removed without official authorisation.

2.2 APPROVAL

2.2.1 To achieve and maintain MAFBNZ approval as a testing laboratory, the applicant laboratory must also meet and continue to maintain accreditation to ISO/IEC 17025.

2.2.2 If the testing laboratory is in New Zealand, and will be testing imported plant material, the applicant will need to register the laboratory as a transitional facility to the MAF standard 152.04.03F "Requirements for Holding and Processing Facilities (Class: Transitional Facilities) for Uncleared Risk Goods". The contact person will advise about the steps required to become registered.

2.2.3 The process to approve GMO testing laboratories includes the following steps:

A. The applicant laboratory will supply to MAFBNZ a document which describes the means by which the facility addresses all of the requirements of this standard.

B. MAF will make an assessment of the following:

1) The detection methods for GMOs including the methods used for sampling, extraction, testing (including procedures to avoid false positive and negative results) and reporting;
2) A description of the standard laboratory operating procedures used and national or international quality systems adhered to;
3) The structural aspects of the laboratory;
4) The equipment available to carry out testing and the calibration of that equipment undertaken to ensure correct performance;
5) The management structure of the laboratory. The role of each staff position in the testing procedure will be described (including the operator, quality manager, and testing personnel), and the competency of staff to undertake these roles;
6) The experience of the laboratory and staff in the area of GMO testing plant material;
7) The independence of the laboratory, i.e. freedom from any commercial interest in the outcome of the testing results.

C. If this evaluation is satisfactory, MAFBNZ will proceed with a pre-approval site audit and assessment.

2.2.3 A pre-approval site audit and assessment will be conducted by MAFBNZ to verify the laboratory and staff's operational competencies as previously assessed remotely in step B1-7.

2.2.4 MAF BNZ will grant approval status when the assessment has been completed and compliance established.

2.2.5 A notice of approval will be sent by the Plant Imports and Exports Group Manager to the Operator of the laboratory. This step will be completed prior to the laboratory carrying out testing to meet MAFBNZ's import requirements.

2.2.6 Maintenance of approval status is subject to ongoing audits by MAFBNZ and maintenance of ISO/IEC 17025 accreditation.

2.2.7 Audits will occur at a frequency and time to be determined by MAFBNZ.

2.2.8 Costs may be recovered from industry (being New Zealand seed importers or the facility requesting approval) in accordance with MAFBNZ cost recovery policy.

2.3 DETECTION METHODS

2.3.1 The testing laboratory will provide MAFBNZ with the documented methods for sampling and testing, and evidence of their validity.

2.3.2 All test methods must be fully documented, periodically reviewed, and amended if necessary.

2.3.3 A minimum of 3200 seeds representatively sampled from seed lots must be analysed and tested according to the most recent version of the MAF Protocol for Testing Seed Imports for the Presence of Genetically Modified Seed.

2.4 Sample Homogenisation

2.4.1 Sample grinding and homogenisation must occur in a room separated from other stages of analysis.

2.4.2 A strict cleaning procedure must be employed to clean the grinding equipment between each sample.

2.4.3 There must be documented procedures to ensure regular laboratory cleaning takes place to prevent cross-contamination.

2.5 Nucleic Acid Extraction.

2.5.1 Sub-samples will be taken from homogenised ground samples and the weights

recorded on the testing certificate.

2.5.2 Nucleic acid extraction methods must be optimised and validated for each species.

2.5.3 Extraction controls must be included to ensure that no cross-contamination has occurred.

2.5.4 The remaining homogenised and whole seed samples must be stored for a period of at least three months should further analysis be required.

2.6 Detection Method.

2.6.1 Test methods must be fully evaluated and verified prior to use on real samples.

2.6.2 Positive and negative testing controls shall be used, using certified reference materials where available. Other reference materials may be used if validated by inter-laboratory comparisons.

2.6.3 The laboratory must determine the Limit of Detection (LOD) for each method prior to use of real samples. If quantitative PCR is performed, the laboratory must also determine the Limit of Quantitation (LOQ) of the method prior to use on real samples.

2.6.4 Controls must be included in each PCR test to ensure that there is no inhibition of the reaction, and the extraction control was not contaminated.

2.6.5 Each sample must be tested in duplicate to ensure reliability of results.

2.6.6 Separate pipettes must be used for all PCR work, and all practicable steps taken to ensure cross-contamination does not occur, such as the use of plugged pipette tips.

2.6.7 The bench top areas must be thoroughly cleaned between different samples.

2.6.8 Calibration procedures must be routinely employed to ensure reliability of pipettes and other critical pieces of equipment.

2.7 Reporting.

2.7.1 Reporting certificates must state the species tested, the number of seeds analysed, the volume of flour sub-sampled for testing, type of PCR test performed, and the results of testing.

2.7.2 All qualitative PCR results must be reported as “positive” or “not detected” for the elements tested.

2.7.3 The Limit of Detection (LOD) and Limit of Quantification (LOQ) must be specified on the testing certificate.

2.7.4 If a result is obtained below the LOQ, the report certificate must include an additional

statement which indicates whether the test was negative or positive for GMO at or above the LOD.

2.8 STANDARD LABORATORY OPERATING PROCEDURES

2.8.1 A description of the standard laboratory operating procedures used by the facility must be provided to MAFBNZ, and the national or international quality systems adhered to.

2.8.2 Laboratories carrying out analyses in accordance with this standard must also be accredited to the most recent version of ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*. Accreditation will be with an Accreditation Body who is a signatory to a Mutual Recognition Arrangement (MRA) of an international or regional co-operation of Accreditation Bodies. The applicant must provide evidence of their accreditation to this standard.

2.8.3 The laboratory must have quality control procedures for monitoring the validity of tests and calibrations. This monitoring may include participation in inter-laboratory comparisons or proficiency testing programmes, but could also include others means such as the regular use of certified reference materials, or replicate tests or calibrations using the same or different methods. Evidence of these procedures must be made available to MAFBNZ to demonstrate competence.

2.9 THE STRUCTURAL ASPECTS OF THE FACILITY

2.9.1 The laboratory must be designed specifically for PCR-based GMO analyses, with a uni-directional flow system comprising of designated areas for each stage of GMO analysis to be conducted.

2.9.2 Additional measures must be implemented as appropriate to prevent contamination of PCR reactions from the sample preparation room, from positive control DNA's used, or by PCR products from other tests conducted.

2.9.3 All rooms must be equipped with separate laboratory clothing and equipment. Strict cleaning procedures should be routinely followed for all equipment and laboratory areas, and these procedures documented and checked by internal audits and tests.

2.10 TESTING EQUIPMENT AND CALIBRATION

2.10.1 Regular cleaning and calibration must be performed on the equipment used for GMO testing, to ensure correct performance. Records of internal and external calibration checks must be kept.

2.11 STAFF COMPETENCIES AND POSITION

2.11.1 The facility must provide MAFBNZ with a summary of the role of each staff position in the testing procedure and the competencies of staff (including the operator) to

undertake these roles.

2.12 EXPERIENCE AND INDEPENDENCE OF THE FACILITY

2.12.1 The applicant must provide MAFBNZ with information on the experience of the facility and staff in the area of GMO testing of plant material, and documentation which demonstrates the independence of the facility i.e. freedom from any commercial interest in the outcome of testing results.

2.12.2 The facility must be non-aligned on issues surrounding the GMO debate.

2.13 MANAGEMENT

2.13.1 The organisation responsible for the operation of the testing facility must have a clearly established management structure with one person (i.e. the operator) having overall responsibility for the operation of the facility, including testing of material and documentation of results.

2.14 RECORDS

2.14.1 The operator of the testing facility must keep records of:

a. the date of entry of the material into the facility,

b. the origin, quantity and identity (species, cultivar, batch/lot) of the material tested,

c. the tests carried out on the material and the results of these tests,

d. equipment registers and calibration logs,

e. routine cleaning and maintenance of essential equipment,

f. staff competency and training,

g. results from proficiency testing programmes.

2.14.2 Records must be maintained for a minimum of two years and shall be available to MAFBNZ on request.

2.15 ACCESS FOR AUDIT PURPOSES

2.15.1 Access to the testing facility (including records of tests on plant material imported into New Zealand) shall be granted to MAFBNZ upon request.

2.15.2 Consent shall be obtained from customers that all PCR test results, for which the testing has been conducted to meet New Zealand's regulatory purposes, will be available to MAFBNZ on request and during audits.

2.16 AUDIT FOR COMPLIANCE

2.16.1 The facility will be audited to ensure ongoing compliance with this Standard by MAFBNZ at a frequency and time to be determined by MAFBNZ.

2.16.2 A report on each completed compliance audit shall be prepared giving details of the scope of the audit, any instances of non-compliance with this standard, agreed corrective actions and any follow up activities. The report shall be finished within one month of completing the audit and a copy forwarded to the facility operator and the Import Standard Group Manager.

2.16.3 Instances of non-compliance will be classified by MAFBNZ according to the severity with which they affect the ability of the testing facility to operate according to the Standard. Examples of minor non-compliance might include changes in structural aspects of the facility without notification, whereas major/critical non-compliance would include failure to correctly identify GMO contamination, or inability to maintain suitable procedures to prevent cross-contamination. Isolated instances of non-compliance are likely to be dealt with by agreeing corrective actions but repeated instances of minor non-compliance and major/critical non-compliances may lead to the suspension or termination of MAFBNZ approval to provide testing services.