REPORTING

Detection and Identification of LMOs

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REPORTING

Goal:

Provide instructions or written notifications according to Laboratory policy in compliance with national and international regulations and practices

REPORTING

- Overview
  - Laboratory policy on sample file content
  - Report writing
  - Technical and administrative review
  - Report issuance
  - Compliance with set standards
  - Confidentiality

LABORATORY POLICY ON SAMPLE FILE CONTENT

1. Purpose of sampling
   - General Market surveillance
   - Custom control
   - Monitoring
   - Risk Assessment
   - Transboundary Movement

LABORATORY POLICY ON SAMPLE FILE CONTENT

- 2. Role of Laboratory
  - National reference laboratory
  - Reference laboratory
  - Service / commercial laboratory
    - testing / certification
    - export purpose / trade
    - Public / private

REPORT WRITING

- QUESTIONS:
  - Specific / general report ?
  - Sampling – responsibility of laboratory or client?
  - Needs of the clients?

REPORT WRITING

- Matrix used
- Summary of sampling
- Summary of testing
  - (Additional information: event specific method used, the information on the safety assessment of the targeted event)

REPORT WRITING

- Result
- Specific based on scope and test conducted
  - e.g based on 35S negative does not mean it is non GM
  - Report should clearly specify that tests conducted, sample found negative
  - Clear mention of LOD e.g 0.1%

REPORT WRITING

- Purpose of testing
  - Detection
  - Identification
  - Quantification
    - Threshold requirement

REPORT WRITING

- Report is specific based on the applicant / customer needs:
  - detect / identify / quantify
- SOP number (name) should be mentioned if required
- Disclosure of measurement of uncertainty if required

TECHNICAL AND ADMINISTRATIVE REVIEW

- Approved by Technical Manager
- Authorised signatory as per Quality Manual

REPORT ISSUANCE

- Hard copy sign by authorized signatory
- Soft copy
  - Scanned copy in pdf

COMPLIANCE WITH SET STANDARDS

- As per reference method e.g ISO 17025 or country national standard

NABL102.....

NABL 102

NABL

NATIONAL ACCREDITATION
BOARD FOR TESTING AND
CALIBRATION LABORATORIES

SPECIFIC CRITERIA *for* BIOLOGICAL TESTING LABORATORIES

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CONTENTS

10. Reporting the Results (ISO/IEC 17025 Clause 5.10)

10.1 Test Records

An adequate test record system in accordance with the various clauses of ISO/IEC 17025, e.g. 4.13, 5.4.7 is essential. Most laboratories have developed forms (proforma sheets) for all their routine testing. These are generally the preferred option as their use prompts the recording of all the required information, maintains consistency and increases recording efficiency.

10.2 Test records in the form of workbooks/worksheets shall be controlled and authorized by designated key technical person and lab should ensure the traceability of raw data to the final report.

10.3 Test Reports

10.3.1 Clause 5.10 of ISO/IEC 17025:2005 standard sets out the requirements for test report issued by testing laboratories.

10.3.2 Test reports must give the customer all relevant information and every effort should be made to ensure that the test report is unambiguous. All information in a test report must be supported by the records pertaining to the test. All information required to be reported by the test specification must be included in the report.

10.3.3 It is important to note that in many instances the test standards, regulatory requirements and industry accepted practice will determine the report format and content.

10.3.4 Laboratories must retain an exact copy of all reports issued. These copies must be retained securely and be readily available for the time specified in the laboratory's documented policies.

10.3.6 Where an estimate of the uncertainty of the test result is expressed on the test report on demand, any limitations (particularly if the estimate does not include the component contributed by the distribution of microorganisms within the sample) have to be made clear to the customer.

10.3.7 Laboratories carrying out GMO testing activities with PCR shall accurately describe the primer sets used and the results obtained. The specificity of the target sequence shall be reported, i.e. '35S promoter: detected', or Roundup Ready: not detected' or 'Bt-176: not detected' instead of a general statement 'does not contain GMO'. The latter wording would imply that primer sets covering all potential GM events had been tested. Similarly, quantitative results shall be reported as 'x.x % of Roundup Ready Soybean' instead of 'x.x % GM material'.

10.3.8 When test results are below the reporting limits, an indication of the reporting limits shall be given in test reports.

10.3.9 The sample preparation procedure should be given for the proper interpretation of test results in GMO testing laboratory's test reports.

10.3.10 NABL symbol in the test reports shall be used in accordance with NABL 133.

10.4 Electronic Reporting

Traditionally, laboratories issued test reports in hard copy format with manual signatures. With increased use of electronic media such as email and the Internet, and the use of electronic databases, laboratories are now issuing the reports electronically. Such practices challenge the generally accepted reporting criteria for accredited laboratories.

10.4.1 ISO/IEC 17025: 2005 clause 5.10.7 attempts in a general way to specify the specific requirements for electronic reporting. While it is difficult to specify in detail a set of requirements to address every eventuality (as laboratories will tend to develop electronic reporting systems to suit their own circumstances and those of their customers), the following is intended to provide guidance on common issues of concern.

10.4.1.1 Transmission of Report

It is the responsibility of the issuing laboratory to ensure that what was transmitted electronically is what the customer received.

Email systems have proven to be robust in this regard, but laboratories need to consider whether customers will have the appropriate software and version to open attachments without corruption.

Laboratories should verify (at least initially, and periodically thereafter is recommended) the integrity of the electronic link e.g. by asking the customer to supply a copy of what was received and comparing it with what was transmitted. It is also important that the laboratory and its customer agree as to which parts of the electronic transfer system they are responsible for and the laboratory must be able to demonstrate data integrity at the point the data comes under the control of the customer.

CONFIDENTIALITY

- Duly coded samples
- Sample reception officer should not be part of report writing or testing process

REPORTING

THANK YOU