Module 6:

REPORTING

**Contents of this module**

Introduction

Laboratory documentation requirements

Report writing sections and contents

1. Report introduction

2. Summary of sampling handling procedures

3. Summary of preparation method

4. Results of the analysis

Technical and administrative review

Report issuance

References

**Introduction**

The outcome of a sample analysis is presented in the form of a written report prepared by laboratory officials. The report is intended to inform the requesting authority of the laboratory’s findings regarding whether or not LMOs are present in the sample, and when suitable, estimated quantities are informed. The report is written according to laboratory policy[[1]](#footnote-1) in compliance with national and international regulations and practices.

A well drafted report is a vital component of the laboratory’s work. It is the primary channel of communication between the laboratory and the requesting authority. A well written report aims to transmit an interpretation of the complex scientific data generated by the laboratory in a clear and concise manner without the use of potentially confusing scientific jargon.

While the format of the report may be presented in numerous ways, there are, nonetheless, several key elements that should be included to ensure that the report is thorough and comprehensive. Additional information can be included to supplement the information contained in the report, based on the national regulatory requirements and the laboratory’s policy.

**Laboratory documentation requirements**

A well compiled laboratory case file is a key component in facilitating the drafting of an informative and through report. It allows for efficient traceability from the raw data to the final report and is therefore important to ensure that the case file is complete and contains all the relevant information needed. All the information in a case file should be compiled in such a way that any other trained laboratory member can follow and understand all the steps and decisions taken during the analysis.

While variations do exist between laboratories in with respect to the level of detail included in a case file, there are a few basic pieces of information that comprise a thorough case file. This may include:

* *Case submission information:* This is a standard form that is to be submitted along with the samples by the authority requesting the testing. The form should include date of sample receipt, name and contact information of the requesting authority, a general description of the items received such as sample type, sample matrix and sample weight, the name and contact information of the laboratory receiving officer, as well as information on the sample’s chain of custody and packaging. Upon the submission of a case to the laboratory a file number should be assigned in order to facilitate administrative follow up and as part of laboratory good management practices.
* *Test record information:* raw data from laboratory testing is normally recorded on standard work forms that are developed by the laboratory. Such forms encourage consistent and standard recording of required information and facilitate the traceability of raw data. The forms are compiled in the relevant laboratory case file along with relevant references to the location of electronic data which can be referred to as needed while drafting a report.
* *Case report:* once the report is written, it also becomes a component of the case file and a copy is retained within the file.

**Report writing sections and contents**

The contents and scope of the report may vary based on the specific requests made by the national authority that is requesting the testing. This will influence both the types of tests carried out and the specificity of the details included in the report in order to adequately answer the questions posed by the requesting authority. The following points are guidelines for the minimum content that may be considered for inclusion in the report. Several of these pieces of information also make up a major component of the case file, which highlights the importance of ensuring that the case file is complete as the analysis takes place.

1. ***Report introduction***

The introductory section of the report provides the reader with a general description of the background of the case. It may be useful to give the reader an overview of the purpose of the testing, along with the requests and/or instructions given to the lab by the requesting authority. For example, the requesting authority may ask for testing for the presence of LMOs in general (screening), or for performing the analysis for the identification and quantification of the specific LMOs that may be present in a sample.

This section should also include logistic information pertaining to the case such as the laboratory’s unique identification numbers for the case and its associated specimens; the name of the requesting authority; the date the specimens were received by the laboratory; the condition in which the specimens arrived, and finally the date the report was issued.

1. ***Summary of sample handling procedures***

The description of the sample submitted for testing and unambiguous identification is an important component of the report. This is relevant to provide the reader with the context in which the tests are being carried out *vis-a-vis* the quality of the sample, as it was submitted to the lab. The summary may include information on whether or not the size of the sample was adequate to carry out the analyses requested, as well as information on the sample matrix from which it was taken, and the visual presence of contaminants. Any possible limitations arising from a poorly submitted sample may affect the results obtained by the laboratory, and therefore, will have to be disclosed within the report. These elements will serve to identify sources of uncertainty and aid to data interpretation.

Further to this description, additional information shall be included regarding the procedures for laboratory sub-sampling techniques and sample processing. These additional manipulations of the sample influence the overall quality of data and conclusion of the report and, as such, should be disclosed within the report. An example of appropriate phrasing for this includes “A 2Kg sample of maize grains was submitted to the laboratory for analysis. The whole sample was homogenised following the procedure outlined in the laboratory SOPs for processing maize grains and mixed. From the homogenized sample a 10g subsample was used to…”

1. ***Summary of preparation method***

The report should clearly specify what tests were conducted on the sample in order to provide the reader with the context within which the data was interpreted. This includes, for example, a description of the methods and analyses that were used to investigate for the presence of LMOs. Furthermore, the inclusion of information on reference parameters such as the specificity, and sensitivity (e.g. detection or quantification limits) is also useful. This can be done by listing the procedure’s laboratory reference number in the report, for example “…a 10g subsample was used to extract DNA using method number NO-1234…” or “…genetic sequences for NOS terminator were detected using method number NO-5678…” Similarly, reference to the specific screening matrix that was utilized to analyse the results would be useful information to add to the report.

In some laboratories, an annex is included with the report to provide the reader with a more detailed technical summary of the methods used including an explanation of the experimental design and the rationale behind the choice of analytical tests that were used to analyse the sample.

1. ***Results of the analysis***

The results and conclusions of the report provide a description and interpretation of the analytical findings produced by the laboratory. Laboratory personnel that are responsible for drafting the report should take into consideration the intended recipients, which may include individuals who may not have a scientific background, such as customs officials. It is therefore important that the report is presented in a well-structured and understandable manner that allows for an easy exchange of information. This can be achieved through the use of standardised terminology to explain the analytical data to the reader. Standardised terminology for reporting analytical data is given the ISO standards (ISO 21569, ISO 21570, ISO 24276) and in a ENGl document (http://gmo-crl.jrc.ec.europa.eu/ENGL/docs/WG-DIR-Final-Report.pdf).

A brief glossary or an appendix might serve this purpose. Therefore accurate terminology is important as it allows for clearer communication of results without generating confusion or giving misleading information.

An example of appropriate terminology regarding the detection of an LMO using an event specific method could be *“the sample tested positive with the […] method that is specific to […] LMO”* rather than *“the sample is…”*.

Furthermore, caution must be observed when test results may be subject to inferred interpretation. For example, if laboratory protocols test only for the presence of an LMOs using element specific methodology or some construct specific methodologies then it would not be appropriate to speculate as to the presence of a particular LMO not being tested. It can only be reported that “*the sample tested positive with the XXX method that is specific to […] genetic element”*.

If however an appropriately validated screening matrix is used to infer the presence of a specific LMO when using a set of element specific methodologies, then, terminology such as “the sample was found to contain…”can be used. It must be noted that in such cases, the report should also specify if it is possible that the result is ambiguous due to potential mixing or due to the presence of genetically modified material from another commodity, for example LM maize that has been intentionally or unintentionally mixed with LM soy.

In cases where the analysis of a sample indicates that the sample does not contain an LMO, care has to be taken when reporting the data so that that the reader understands that a negative result has to be interpreted in the context of the technical limitations of the test preformed. Therefore, terminology such as “not detected” or “none detected” may be used. This type of terminology is preferable to statements like LMO is “not present”, “does not contain” or “negative” because it provides the reader with a framework that recognises the limitations of the methods performed, and that the LMO may be present in quantities that are below the limits of detection. To provide additional clarity to the reader, it is useful to state within the report what the limit of detection of the test is, together with the conditions in which the analysis is performed. It is also particularly important, in such cases, that control tests are well documented, as they provide relevant information on the quality of the data.

An example of a negative report for LMOs would therefore indicate: A 2Kg sample of maize grains was submitted to the laboratory for analysis. The whole sample was ground up and mixed. A 10g subsample was used to extract DNA using method number NO-1234. No genetic sequences from Roundup Ready Maize were detected using method number NO-5678 with a detection limit of 0.01% cp/cp in this matrix.

And a positive report would similarly indicate: A 2Kg sample of maize grains was submitted to the laboratory for analysis. The whole sample was ground up and mixed. A 10g subsample was used to extract DNA using method number NO-1234. Genetic sequences for the presence of Roundup Ready maize were detected using method number NO-5678 with the Waiblinger Screening matrix.

If quantitative analyses were performed, amounts may be provided as relative or absolute values, and calibration curves or standard reference materials used need to be mentioned.

**Technical and administrative review**

A *technical review* is an in-depth review of the analysis records that is carried out prior to the issuance of a report to confirm the validity of results and conclusions.

The technical review is carried out with the view to:

* Ensure that the appropriate analyses have been conducted.
* Ensure that the conclusions of the reporting analyst are reasonable, consistent with the documented data, and within the constraints of validated scientific knowledge.
* Confirm that verifications have been documented.
* Ensure that technical language in the report is clear, accurate, and complete.
* Ensure there is sufficient supporting documentation.

In addition, the technical reviewer and the analyst who drafted the report are equally responsible for ensuring the accuracy of the technical aspects of the case record.

An *administrative review* is a procedure that checks the case file documentation and reports for consistency with laboratory policy and for editorial correctness prior to issuing a report to the requesting authority.

An administrative review ensures that the content of the report follows laboratory policy and procedure by ensuring that the language in the report is clear, accurate, and complete, in addition to proofreading the report for clerical errors. Furthermore, the administrative review checks that the technical review has been properly conducted and documented.

Technical and administrative reviews may be combined as one process and carried out by the same person. However, neither the technical nor the administrative reviews are to be conducted by the analyst who completed the work.

**Report issuance**

Once the technical and administrative reviews have been completed and documented in the case file the report is signed by an authorised signatory as the person(s) accepting responsibility for the content of the report, as per laboratory policy. The authorised signatory is to include their signature and title, or equivalent identification, printed name and laboratory of employment.

Laboratories must retain an exact copy of all reports issued within the relevant case files. These copies must be retained securely and be readily available for the time period specified in the laboratory’s documented policies, since they are subject of audit and review.

In the event that an amendment has to be made to a report after it has been issued, it has to be communicated in the form of a supplementary report that quotes the original report as a reference. If it is necessary to issue a replacement report, this should be uniquely identified and should contain a reference to the original document that it replaces.

**References**

National Accreditation Board for Testing and Calibration Laboratories, India; Specific Criteria for Biological Testing Laboratories; 2012

United Nations Office on Drugs and Crime (UNODC); Guidance for the Implementation of a Quality Management System in Drug Testing Laboratories; 2009

National Association of Testing Authorities, Australia; Biological Testing ISO/IEC 17025 Application Document, Annex D: Accreditation of facilities testing for genetically modified organisms (GMO); March 2013

National Association of Testing Authorities, Australia; Criteria for Accreditation of Laboratories Testing Genetically Modified Organisms; 8.G13 GMO Guidelines / Issue 2 / March 2006

ISO 21569 Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Qualitative nucleic acid based methods

ISO 21570 Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Quantitative nucleic acid based methods

ISO 21571 Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- Nucleic acid extraction

ISO 21572 Foodstuffs -- Molecular biomarker analysis -- Protein-based methods

ISO 24276 Foodstuffs -- Methods of analysis for the detection of genetically modified organisms and derived products -- General requirements and definitions

JRC Technical Reports (2017) Detection, Interpretation and Reporting on the presence of authorised and unauthorised genetically modified materials. (http://gmo-crl.jrc.ec.europa.eu/ENGL/docs/WG-DIR-Final-Report.pdf

1. Write something about this in QA section and reference (MQ: Reference to module addressing implementation of quality (system) in the laboratory and/or accreditation) [↑](#footnote-ref-1)