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EPPO STANDARD ON DIAGNOSTICS

PM 7/130 (2) Guidelines on the authorization of laboratories to perform diagnostic activities for regulated pests

SPECIFIC SCOPE

These guidelines describe the process and requirements for authorization of a laboratory by a National Plant Protection Organization (NPPO) to perform diagnostic activities for regulated pests. This Standard should be used in conjunction with PM 7/76 *Use of EPPO Diagnostic Standards*.

SPECIFIC APPROVAL AND AMENDMENT

Approved as an EPPO Standard in 2016-09.[1] Revised in 2024-09 following the revision of the NAPPO Standard RSPM 9 on the Authorization of Laboratories for Phytosanitary Testing (NAPPO, 2021).

Authors and contributors are given in the Acknowledgements section.

1 | INTRODUCTION

In many countries the diagnostics for regulated pests are performed in laboratories of the NPPO or in governmental agencies/institutes working for the NPPO (hereafter called NPPO laboratories). However, in some countries NPPOs authorize other laboratories to perform pest diagnostic activities, and this is an increasing trend in the EPPO region.

In 2016, guidelines for the authorization of laboratories were established to ensure harmonization across the EPPO region. Specific regulations have been established in some countries (e.g. the regulation 2017/625/EU[2] for EU countries).

[1]This Standard was initially prepared based on the NAPPO Standard RSPM 9 on the Authorization of Laboratories for Phytosanitary Testing (NAPPO, 2009).

[2]In the regulation 2017/625/EU, authorization of laboratories is referred to as the designation of official laboratories (article 37).

2 | RESPONSIBILITIES AND TASKS OF THE NPPO

2.1 | Authority

The NPPO should have the authority to authorize laboratories to perform diagnostic activities for regulated pests, and to suspend or revoke the authorization of a laboratory that does not comply with the requirements as described in Section 3.

The NPPO may delegate all or part of the management of the authorization process to another competent body.

2.2 | Responsibility of the NPPO

The NPPO should verify that the laboratory will ensure the safety of its activities in order to prevent the spread of quarantine pests covered in the scope of authorization, in accordance with EPPO Standard PM 3/64 *Intentional import of organisms that are plant pests or potential plant pests* or the NPPO's requirements (EPPO, 2006). The NPPO should establish a procedure for laboratory authorization and have the necessary information and resources to implement and maintain this procedure.

The procedure should include elements such as:

- A list of basic criteria to be fulfilled by laboratories prior to the authorization (see Section 3) or renewal of authorization where appropriate.
- The assessment of the laboratories prior to authorization to check the fulfilment of the basic criteria for authorization of laboratories (e.g. see Section 3).
- A regular risk-based monitoring programme for authorized laboratories. The monitoring programme may include audits, proficiency testing, checking of blind samples, document or records review, follow-up on reported results (e.g. confirmation by reference laboratories) or other suitable means. Audits performed in the framework of ISO 17025 accreditation may also be considered in the monitoring programme.
- Basic criteria for suspension and/or revocation of the authorization in the case of work that does not conform to the agreement should be a part of the procedure. Where

monitoring identifies a non- conformity, the NPPO should examine the non-conformity documentation and determine how to proceed as per the legal framework established by each NPPO. The NPPO should suspend some or all phytosanitary testing activities if the non-conformity is not reasonably addressed or continues to pose a risk. Note that revocation of the authorization may be possible in other circumstances e.g. if the NPPO no longer needs authorized laboratories.

A flow diagram summarizing the procedure for non NPPO laboratories is available in Figure 1.

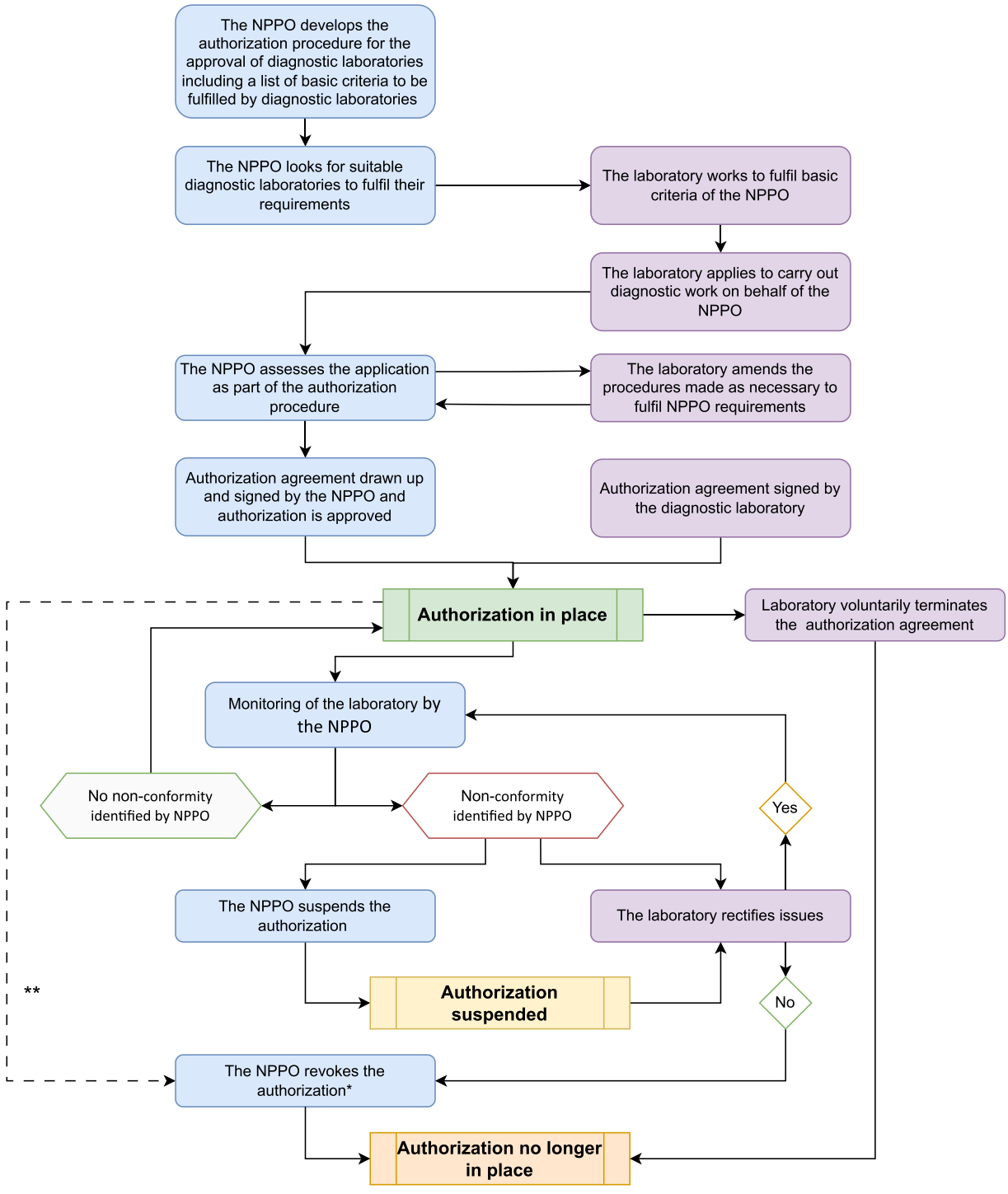

FIGURE 1 The different steps of the procedure for laboratory authorization of non NPPO laboratories.

2.3 | Authorization agreement

The NPPO should establish a formalized agreement between the NPPO and the authorized laboratory specifying the rights, obligations and requirements of both parties such as:

- The scope of authorization (details on the diagnostic activities for regulated pests authorized, such as: pests, matrices covered, tests and flow charts to be used).
- The requirements and obligations of the laboratory (see Section 3).
- Timelines for delivering diagnostic results and reporting mechanisms.
- Conditions for authorization and termination; in particular, procedures and criteria for suspension, reinstatement or revocation of authorizations.
- Confidentiality and impartiality requirements.
- The obligation to fulfil any of the NPPO legal requirements.

The agreement should be valid for a defined period of time and be formally authorized (signed) by senior management in both organizations.

The agreement may be formally renewed subject to satisfactory performance (as determined by the NPPO), and on acceptance of both organizations.

The NPPO should specify if an authorized laboratory is allowed to subcontract its diagnostic activities. NPPO documentation relating to the authorization process should be available to other NPPOs upon request.

The laboratory may voluntarily terminate the authorization agreement with the NPPO. Upon termination, the laboratory should immediately inform the NPPO and should not perform any phytosanitary testing activities authorized in the original agreement.

A formalized authorization agreement may not be needed in the case of NPPO laboratories.

3 | SPECIFIC REQUIREMENTS/ OBLIGATIONS FOR THE LABORATORY

In order to be authorized to perform diagnostics for regulated pests, laboratories should agree to fulfil a number of obligations including the ones listed in Section 3.1. prior to authorization. Laboratories should also meet the requirements detailed in Section 3.2 before applying for authorization. If the laboratory is accredited under ISO 17025 for activities covered under the scope of the authorization, it is considered to fulfil the technical requirements described for these activities below.

3.1 | General requirements/obligations

The laboratory should fulfil the following requirements/obligations:

- The obligation to maintain proper documentation and records of each test performed.
- The obligation to notify the NPPO of any suspected occurrence or positive test result for a regulated pest according to national regulations.
- Requirements for keeping the remainer of test material (e.g. part of the original sample, plant material extract or nucleic acid extract) for possible confirmation.
- The obligation to report to the NPPO major changes in the authorized laboratory that might affect the authorization agreement or the performance of diagnostic activities (e.g. change of relevant personnel, management structure, equipment, organization of the laboratory, and methods/tests, and nonconforming results in ILCs).

3.2 | Technical requirements

3.2.1 | Quality system

The laboratory should fulfil the management requirements included in the Section 3 of PM 7/84 *Basic requirements for quality management in plant pest diagnostic laboratories* (EPPO, 2021a).

3.2.2 | Personnel

The laboratory staff should comply with the technical requirements for personnel as described in the section 4 of PM 7/84 (EPPO, 2021a).

3.2.3 | Tests

The laboratory should perform tests which are selected according to PM 7/98 *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* (section 5.4.2 'Selection of tests') (ISO 17025 point 5.4.2) (EPPO, 2021b) and agreed with the NPPO.

3.2.4 | Verification of competence

The laboratory should perform all proficiency testing, checking of samples or other competence testing required by the NPPO and submit results as specified by the NPPO. Verification of the competence of the laboratory should be conducted in accordance with PM 7/98, point 5.4.5 'Verification of the performance of

the laboratory to undertake a specified test (ISO 17025, 2017, point 7.2.1.5)' (EPPO, 2021b).

3.2.5 | Subcontracting

Subcontracting of testing by the authorized laboratory is permitted if documented in the quality system manual (PM 7/84, EPPO, 2021a) and approved by the NPPO. The requirements of this Standard also apply to the subcontracting laboratory.

3.2.6 | Facilities and equipment

The accommodation and environmental conditions should comply with the technical requirements as described in the relevant section of PM 7/84 (EPPO, 2021a).

Laboratory facilities should be approved by the NPPO. A comprehensive initial on-site visit and subsequent monitoring visits to authorized laboratories are required to ensure that the technical or quality requirements of the NPPO are met.

Calibration and monitoring of equipment should be documented and performed according to the guidance given in PM 7/84 (EPPO, 2021a). Records on calibration and equipment maintenance should be made available to the NPPO upon request.

3.2.7 | Records and reporting

Laboratories should provide to the NPPO, upon request, all relevant documentation linked to the diagnostic activities. This documentation includes reports of all tests performed on behalf of the NPPO, equipment records, training records, quality control records and participation in inter-laboratory comparisons. Sample submission forms, worksheets and records of test results, including all original observations and raw data, should be kept on file. Records should be kept in such a way as to ensure integrity and traceability of test data by the laboratory for the period specified by the NPPO. Detailed records should ensure that errors can be identified, and corrective actions can be taken, as necessary. Guidance on reporting on a diagnostic activity is provided in EPPO Standard PM 7/77 *Documentation and reporting on a diagnosis* (EPPO, 2019).

ACKNOWLEDGEMENTS

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