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Diagnostics
Diagnostic

PM 7/130 (1) Guidelines on the authorization of laboratories to perform diagnostic activities for regulated pests

Specific scope

This guideline describes the process and requirements for authorization of a laboratory by a National Plant Protection Organization (NPPO) to perform diagnostic activities for regulated pests.[1]

Specific approval and amendment

Approved as an EPPO Standard in 2016-09.

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. The EPPO Working Party on Phytosanitary Regulations suggested that guidelines for the authorization of laboratories should be established to ensure harmonization across the EPPO region.

This guideline may also be relevant for authorization of NPPO laboratories.

2. Responsibilities and tasks of the NPPO

The NPPO should have the authority to authorize laboratories to perform diagnostic activities for regulated pests. A formal application for authorization should be requested by the NPPO. The NPPO should have the authority 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.

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, 2006b).

The NPPO should establish a laboratory authorization plan, and have the necessary information and resources to implement and maintain this plan.[2]

The plan should include elements such as:

- The establishment of a formalized agreement between the NPPO and the authorized laboratory specifying the rights and obligations 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 obligation to maintain proper documentation and records of each test performed by the authorized laboratory.
  - The obligation to notify any suspected occurrence or positive test result for a regulated pest according to national regulations.
  - Requirements for keeping test material for possible confirmation.
  - 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 report to the NPPO major changes in the authorized laboratory that might affect the perfor-

[1]This Standard was initially prepared based on the NAPPO Standard RSPM9 on the Authorization of Laboratories for Phytosanitary Testing (NAPPO, 2009).

[2]A template will be prepared in 2017.

mance of diagnostic activities (e.g. change of personnel, equipment, organization of the laboratory).
- A regular monitoring programme for authorized laboratories. The monitoring programme may be based on audits, proficiency testing, checking of samples or other suitable means.
- 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 plan.

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.

3. Specific requirements for the laboratory

In order to be authorized to perform diagnostics for regulated pests, laboratories should meet the requirements detailed in the sections below before authorization is applied for.

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. Quality system

The laboratory should fulfil the requirements included in PM 7/84 *Basic requirements for quality management in plant pest diagnosis laboratories* (EPPO, 2007).

3.2. Personnel

The laboratory staff should comply with the technical requirements for personnel as described in the relevant section of PM 7/84 (EPPO, 2007).

3.3. 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, 2014) and agreed with the NPPO.

3.4. 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 5.4.4 'Verification of the performance of the laboratory to undertake a specified test'.

3.5. Subcontracting

Subcontracting of testing by the authorized laboratory is permitted if documented in the quality system manual (PM 7/84, EPPO, 2007) and approved by the NPPO. The requirements of this Standard also apply to the subcontracting laboratory.

3.6. 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, 2007).

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, 2007). Records on calibration and equipment maintenance should be made available to the NPPO upon request.

3.7. 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. Guidance on reporting on a diagnostic activity is provided in EPPO Standard PM 7/77 *Documentation and reporting on a diagnosis* (EPPO, 2006a).

Acknowledgements

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References

EPPO (2006a) PM 7/77 (1): Documentation and reporting on a diagnosis. *EPPO Bulletin*, **36**, 459–460.

EPPO (2006b) PM 3/64 (1): Intentional import of organisms that plant pests or potential plant pests or the NPPO's requirements. *EPPO Bulletin* **36**, 191–194.

EPPO (2007) PM 7/84 (1) Basic requirements for quality management in plant pest diagnosis laboratories. *EPPO Bulletin* **37**, 580–588.

EPPO (2014) PM 7/98 (2): Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity. *EPPO Bulletin*, **44**, 117–147.

NAPPO (2009) The Authorization of Laboratories for Phytosanitary Testinghttp://www.nappo.org/en/data/files/download/PDF/RSPM9-Rev10-08-09-e.pdf (last accessed 19 January 2016).