A flexible scope on phytosanitary diagnostics

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National Reference Centre (NRC)
National Plant Protection Organization (NPPO-NL)
The Netherlands
Quality management systems

• Quality management systems have become an integral part of plant health laboratories

• Over the last decade, many plant health labs became accredited according to ISO 17025:2005

• The Dutch NPPO started accreditation under 5 fixed scopes for several years

• Since December 2016, the NPPO-NL labs became accredited under phytosanitary orientated flexible scope
Old (fixed) accreditation scopes

<table>
<thead>
<tr>
<th>Nr.</th>
<th>Type of material</th>
<th>Method(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><em>Lycopersicon esculentum</em> (tomato)</td>
<td>Isolation of <em>Clavibacter michiganensis</em> subsp. <em>michiganensis</em> in symptomatic material (stem) from tomato by plating on semi-selective media.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Identification of <em>Clavibacter michiganensis</em> subsp. <em>michiganensis</em> by IF, real-time PCR and pathogenicity test</td>
</tr>
</tbody>
</table>

2. *Andean potato latent virus* (APLV)
3. *Phytopthora ramorum*
4. *Thrips palmi*
5. *Ditylenchus dipsaci*
Why explore the possibilities of a phytosanitary oriented flexible scope?

Diagnostic activities are characterized by a high diversity of organism-matrix combinations. Per combination the number of samples is low.
Why explore the possibilities of a phytosanitary oriented flexible scope?

- Unfeasible to become accredited for all combinations under a standard fixed or flexible scope

- Broad scientific and practical expertise needed for the diagnostic process does not get recognition under the current scopes
  - Diagnostic process is based on knowledge and can be a combination of (e.g.) symptoms, literature, tests, morphology

- Extensive validation and 2nd/3rd line controls for each single test performed for all combinations: not possible
Accreditation scopes

- In consultation with the Dutch Accreditation Board (RvA), a phytosanitary oriented interpretation within the existing flexible scopes was sought.

- RvA uses ILAC G18 as reference for defining accreditation scopes.

<table>
<thead>
<tr>
<th>Fixed scope</th>
<th>Flexible scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Process is fixed</td>
<td>- Process is flexible</td>
</tr>
<tr>
<td>- Detailed description of type of test, organism(s) and matrix</td>
<td>- Generic description</td>
</tr>
<tr>
<td>- Based on validation</td>
<td>- Flexibility concerning object, or matrix or sample.</td>
</tr>
<tr>
<td></td>
<td>- On-going validation</td>
</tr>
</tbody>
</table>
The phytosanitary oriented flexible scope

- Scope defines generically matrices, organism groups and methods
- Flexibility on organisms within organism groups, specific matrices within the generic description, and tests used under the defined methods

<table>
<thead>
<tr>
<th>No</th>
<th>Material or product</th>
<th>Type and methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Plant material and Arthropods</td>
<td>Identification of Arthropods using Morphology, Real-time PCR, PCR-Sequencing</td>
</tr>
<tr>
<td>2</td>
<td>Plant material and cultures</td>
<td>Identification of Plant pathogenic bacteria using Isolation, IF, Real-time PCR, PCR, Pathogenicity testing</td>
</tr>
<tr>
<td>3</td>
<td>Plant material and nematodes</td>
<td>Identification of Nematoda using Extraction, Morphology, Real-time PCR</td>
</tr>
<tr>
<td>4</td>
<td>Plant material and cultures</td>
<td>Identification of Oomycota using Isolation, Morphology, Real-time PCR</td>
</tr>
<tr>
<td>5</td>
<td>Plant material</td>
<td>Identification of plants using Morphology, PCR-Sequencing</td>
</tr>
<tr>
<td>6</td>
<td>Plant material</td>
<td>Identification of van plant viruses and viroids using Bioassay, DAS-ELISA, PCR, Real-time PCR, PCR-Sequencing</td>
</tr>
</tbody>
</table>
Results
P-302 Diagnosis
Results can be issued if at least one validated test is used to conclude the final result.

Validation
P-315 Research, Development and Validation of methods
On method level an extensive validation is performed addressing all performance characteristics.
Individual tests are validated as much as necessary and relevant for the intended use.

Expertise
P-301 Training and qualification of personnel NRC
Choices of methods and analysis of the results during the diagnostic process are based on expertise and competence of specialists. Expertise is documented and maintained.

Assurance
P-322 Quality assurance of diagnoses
1st line controls are in place. 2nd and 3rd line assurance are yearly being conducted on method level and organism group. Selection is being made on risk and diversity of species and documented in an multiple year assurance plan. Also the diagnostic process is assured.

Organisms under accreditation
P-302 Addition of activities under flexible scope NRC
Organisms can be added to internal list of accreditation if:
- At least one of the tests used to conclude the final result is validated for the intended use
- Assurance, expertise and internal audit system is organised for the organism

Quality management system
P-399 Quality manual NRC
Fundamental aspects of ISO 17025 are applied, such as management, training, documentation, calibrated and validated equipment, initial checks of reagents etc.
Main principles

• Three main principles are defined that need to be in place for organisms, matrices, and tests included under the flexible scope

• Validation
  › as much as necessary and relevant for intended use

• Expertise
  › Choice of methods and tests based on expertise
  › Experience is documented and continuously updated

• Quality Assurance
  › For all tests 1st line controls are in place
  › 2nd and/or 3rd line controls are performed on method level
  › Selection of 2nd and 3rd line controls is done in a way that assures coverage of a wide range of species, tests, matrices and technicians
• scope of accreditation of NRC

• Internal list of accreditation (see next slide)

  on the 11th of december 2020
  There are 91 organisms under 6 flexible scopes
Placing the diagnostic process central

**R-VIR-000-001 Overview of viruses and viroids under accreditation**

<table>
<thead>
<tr>
<th>Genus</th>
<th>Species</th>
<th>Matrix</th>
<th>Bioassay</th>
<th>DAS-ELISA</th>
<th>PCR</th>
<th>Real-time PCR</th>
<th>PCR-Sequencing</th>
<th>Electron microscopy</th>
<th>r-PAGE</th>
<th>Date of addition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tymovirus</td>
<td>Andean potato latent virus</td>
<td>leaves</td>
<td>TYMO_20160315_TPO</td>
<td>TYMO_20160315_ELISA</td>
<td>+</td>
<td></td>
<td>TYMO_20160315_SEQ</td>
<td>+</td>
<td></td>
<td>20160315</td>
</tr>
<tr>
<td>Tymovirus</td>
<td>Andean potato mild mosaic virus</td>
<td>leaves</td>
<td>TYMO_20160315_TPO</td>
<td>TYMO_20160315_ELISA</td>
<td>+</td>
<td></td>
<td>TYMO_20160315_SEQ</td>
<td>+</td>
<td></td>
<td>20160315</td>
</tr>
<tr>
<td>Pospiviroid</td>
<td>Potato spindle tuber viroid</td>
<td>leaves</td>
<td></td>
<td>POSPI_20160315_PCR</td>
<td>POSPI_20160315_RPCR</td>
<td>POSPI_20160315_SEQ</td>
<td>+</td>
<td></td>
<td>20160315</td>
<td></td>
</tr>
<tr>
<td>Pospiviroid</td>
<td>Tomato chlorotic dwarf viroid</td>
<td>leaves</td>
<td></td>
<td>POSPI_20160315_PCR</td>
<td>POSPI_20160315_RPCR</td>
<td>POSPI_20160315_SEQ</td>
<td>+</td>
<td></td>
<td>20160315</td>
<td></td>
</tr>
</tbody>
</table>

- **Green**: validated test
- **White +**: test not validated to base a result on, but can be used to support the diagnostic process
Experiences: we are happy to share them!
More information:

Thank you for your attention