Flexible scope in Plant Health (phytoflex)

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National Plant Protection Organization (NPPO-NL)
The Netherlands
Why phytoflex?

Diagnostic results 2014

- # organisms
- # organism-host combinations
- # accredited
Why phytoflex?

• Many organism-matrix (host) combinations
• Phytoflex offers..
  - risk-based validation supported by expertise and quality assurance
  - adjusting scope before approval of AB
• Fits in risk-based approach ISO 17025 (2017)
Key principles of phytoflex

Validation
ISO 17025 (2017):
7.2.2.1.C
7.2.1.5 & 6 & 7

Expertise
ISO 17025 (2017):
6.2.5 & 6

Quality Assurance
ISO 17025 (2017):
7.7.1 & 2 & 3
**Targeted samples**
Symptomatic and asymptomatic samples

**Initiate prescribed test(s) or key(s)**

**Non-targeted samples**
Symptomatic samples

**Assessment of characteristics and selection of test(s)/key(s)**

- Analysis
- **Interprete results**
  - Identify a/o confirm
  - **Further research**
  - **Report**

**Further research**
Targeted samples

- Initiate prescribed test(s) or key(s)

Non-targeted samples

- Assessment of characteristics and selection of test(s)/key(s)

Analysis

Interprete results

Identify a/o confirm

Further research

Report
Non-targeted samples

Targeted samples

Validation
Expertise
Assurance

Key principles

Organisms under accreditation

Quality management system

Validation
Expertise
Assurance

Fit for purpose
Validation (risk analysis)

Determine relevant performance characteristics (fit for purpose)

<table>
<thead>
<tr>
<th></th>
<th>Detection</th>
<th>Identification/confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analytical sensitivity</strong></td>
<td>prevent false negatives</td>
<td>covered by detection</td>
</tr>
<tr>
<td><strong>Analytical specificity</strong></td>
<td>detect all variants of target organism (intra-species variation)</td>
<td>distinguish closest relatives (inter-species variation)</td>
</tr>
<tr>
<td><strong>Selectivity</strong></td>
<td>prevent false negatives</td>
<td>prevent false positives</td>
</tr>
<tr>
<td><strong>Repeatability and reproducibility</strong></td>
<td>method level (transferable)</td>
<td>method level (transferable)</td>
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</tbody>
</table>
Expertise

- Important in phytoflex scope
- Competences of staff
- Competences of laboratory, making knowledge available via databases (images, slides, literature, test results)
- Safeguarding knowledge in databases
## Database of bio-assay results

<table>
<thead>
<tr>
<th>Nummer</th>
<th>Genus</th>
<th>Diagnose</th>
<th>qui lok</th>
<th>qui syst</th>
<th>bent lok</th>
<th>bent syst</th>
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<th>P1 syst</th>
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<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Database of nematode x identified in host y

<table>
<thead>
<tr>
<th>Gewas</th>
<th>Ned. Naam Gewa</th>
<th>Nematode</th>
<th>Toelichting</th>
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<tbody>
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<td>Cymbidium</td>
<td>Orchidee</td>
<td>Pratylenchus scribens</td>
<td>Zie bij algemeen.</td>
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<tr>
<td>Cyperus</td>
<td>Cypergras</td>
<td>Meloidogyne</td>
<td></td>
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<tr>
<td>Cytisus</td>
<td>Brem</td>
<td>Meloidogyne hapla</td>
<td>Zie bij algemeen.</td>
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<tr>
<td>Cytisus</td>
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<td>Pratylenchus penetrans</td>
<td>Zie bij algemeen.</td>
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<tr>
<td>Dactyly glomerata</td>
<td>Kropaar</td>
<td>Heterodera bifenestra</td>
<td>Wel waardplant; schaderelatie niet onderzocht. Zie ook bij algemeen.</td>
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<tr>
<td>Dactyly glomerata</td>
<td>Kropaar</td>
<td>Heterodera mani</td>
<td>Wel waardplant; schaderelatie niet onderzocht. Zie ook bij algemeen.</td>
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<tr>
<td>Dactyly glomerata</td>
<td>Kropaar</td>
<td>Meloidogyne naasi</td>
<td>Zie bij algemeen.</td>
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<td>Paratrichodorus teres</td>
<td>Zie bij algemeen.</td>
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<tr>
<td>Dahlia</td>
<td>Dahlia</td>
<td>Aphelenchoides nitzeabosi</td>
<td>Zie bij algemeen.</td>
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</tbody>
</table>
Quality assurance within phytoflex scope

1\textsuperscript{st} line control
- positive and negative control at test level
- second morphological identification

2\textsuperscript{nd} and/or 3\textsuperscript{rd} line control
Unfeasible at test level, because of potentially unlimited number of organism-matrix combinations
- multi-annual rotation of supergroups (family, genus)
- principle each method each year (ELISA, PCR, extraction technique)
- blind samples at process level (diagnostic samples, non-targeted samples)
Documentation of addition to scope based on risk analysis at process level
Thus...

Phytoflex scope potentially

- fits within risk-based approach of ISO 17025 (2017) - expected to be accepted by the Dutch Accreditation Board this year
- enables unlimited number of organism – matrix (host) combinations
Organisms identified 2014 - 2018