Flexible scope experience at NIB in Slovenia

- testing laboratory
- fixed scope since 2003 (GMO)
- flexible scope since 2012 (GMO & 'plant health')

EPPO Workshop on Flexible Scope.
NVWA, Geertjesweg 15, Wageningen (NL), 2017-06-26/28
Scope of accreditation

Testing fields:
- biology, biochemistry (GMO detection)
- microbiology (molecular methods)

Test items:
- foodstuffs
- agricultural products
- biological samples
**Tip obsega:** fleksibilni (možnost uvajanja manjših sprememb metode ali dodatnih vrst preskušancev ali dodatnih parametrov)*

*Type of scope: flexible (possibility of implementing minor modifications of the method or introducing additional types of test items or additional parameters)*

**Mesto izvajanja:** v laboratoriju / **Site:** in the laboratory

**Področja preskušanja glede na vrsto preskušanja**: mikrobiologija (molekularne metode) / Testing fields with reference to the type of test: **microbiology (molecular methods)**

**Področja preskušanja glede na vrsto preskušanja:** živila; kmetijski proizvodi; biološki vzorci / **Testing fields with reference to the type of test item:** foodstuffs; agricultural products; biological samples

<table>
<thead>
<tr>
<th>Št No</th>
<th>Oznaka standarda ali nестandardne preskusne metode</th>
<th>Naslov standarda ali nестandardne preskusne metode in morebitne navezave na druge standardne ali metode</th>
<th>Območje preskušanja, Negotovost rezultata preskušanja (kjer je to pomembno)</th>
<th>Materials; proizvodi Materials; products</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>02D-Pos48 interna metoda in-house method</td>
<td>PCR v realnem času za določanje mikroorganizmov - povzročitelje bolezni rastlin / Real time PCR for testing of microorganisms – plant pathogens</td>
<td>Kvalitativna metoda na osnovi nukleinske kisline v povezavi z internimi postopki / Qualitative nucleic acid based methods in connection with internal procedures: 02D-Pos06 - Ekstrakcija DNA za analizo fitoplasma / DNA extraction for phytoplasma analysis</td>
<td>živila, kmetijski pridelki in biološki vzorci (razen semen) foodstuffs, agricultural produce and biological samples (except seeds)</td>
</tr>
</tbody>
</table>

*Laboratorij lahko po potrebi uvede manjše spremembe metode ali dodatne vrste preskušancev znotraj skupin navedenih v zadnjem stolpcu tabele, ali dodatne parametre v okviru namembnosti metode. Podatke o trenutnem stanju obsega vzdržuje laboratorij. / Laboratory can implement minor modifications of the method or introduce additional types of test items from a group defined in the last column of the table or introduce additional parameters within limits of the purpose of the method as necessary. Details on the actual extent of the scope are maintained by the laboratory.*

List of accredited methods precisely defines methods listed in Annex to the accreditation certificate no. LP-028, and used by the Department of biotechnology and systems biology for detection of microorganisms - plant pathogens.

<table>
<thead>
<tr>
<th>Reference to standard or non-standard testing method</th>
<th>Title of standard or non-standard testing method and eventual relations to other standards or methods</th>
<th>Range of testing</th>
<th>Materials; products</th>
<th>Internal procedure code</th>
<th>Issue</th>
<th>Title of procedure for detection of genetic elements</th>
<th>Method accredited from</th>
</tr>
</thead>
<tbody>
<tr>
<td>02D-Pos48 (issue 06) in-house method</td>
<td>Real time PCR for testing of microorganisms - plant pathogens</td>
<td>Stolbur group, 16SrXII, Stol11 genomic fragment (including BN and MR phytoplasma: 'Ca. P. solani') - qualitative</td>
<td>plants and insects</td>
<td>02D-Pos43</td>
<td>08</td>
<td>Detection of phytoplasmas with real-time PCR</td>
<td>11-10-2012 FD and BN phytoplasma</td>
</tr>
<tr>
<td>02D-Pos06 (issue 08) - DNA extraction for phytoplasma analysis</td>
<td>Qualitative nucleic acid based methods in connection with internal procedures:</td>
<td>Elm yellows group. 16SrV, FD9 genomic fragment (including FD phytoplasma) - qualitative</td>
<td>03-07-2014 AP PD and ESFY phytoplasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>02D-Pos06 (issue 08) – DNA extraction for phytoplasma analysis</td>
<td>AP phytoplasma ('apple proliferation, 'Ca. P. mali', IGS region)</td>
<td>07-07-2015 Maize redness phytoplasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>02D-Pos06 (issue 08) – DNA extraction for phytoplasma analysis</td>
<td>PD phytoplasma ('pear decline, 'Ca. P. pyri', IGS region)</td>
<td>07-07-2015 Maize redness phytoplasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>02D-Pos06 (issue 08) – DNA extraction for phytoplasma analysis</td>
<td>ESFY phytoplasma ('European stone fruit yellows, 'Ca. P. prunorum', IGS region)</td>
<td>07-07-2015 Maize redness phytoplasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- to be added: more detailed definition of matrices
- can extend range of testing, materials tested
- even before an external audit results can be reported as 'accredited'
- validation
Dealing with validation

- internal procedures for **planning** of validation, **validation** and **reporting**
  - in-line with EPPO recommendations
  - implementation of a validated method
  - critical points analysis
  - in-house developed methods
  - comparison with current methods
  - analysis of samples
  - **spiked positive controls**

- **not modular**
  - validation of [DNA extraction + qPCR]
  - GMO: DNA extraction = good → any qPCR
Implementing quality assurance

- different approaches: GMO/phytoplasma/bacteriology
  - use of internal amplification controls (mostly yes)
  - positive isolation controls (used in bacteriology)
  - decisions based on analysis of critical points and generated data
  - useful VS necessary

- internal procedure: managing rarely used methods
  - less than once per year
  - precautionary measures
    - literature review
    - read the relevant documents
    - check chemicals and reagents
    - check instruments
    - use positive and negative controls
Demonstrating expertise

- performance
  - testing
    - on-time analysis
    - positive findings / interceptions / detection of outbreaks
    - blind samples
    - results of controls
  - proficiency tests

- validation data
- international collaboration
- peer-reviewed publications
Conclusions

- Broad flexible scope based on a methodology (real-time PCR) and a range of matrices
- Answering 'is this present?'
- Additions supported by additional validation data
- On-going discussions about 'the Scope'
  - Should testing of everything within the scope be possible without additional validation data?
- Not fully exploited yet
  - E.g. reproducibility and repeatability so far determined for all accredited qPCRs