

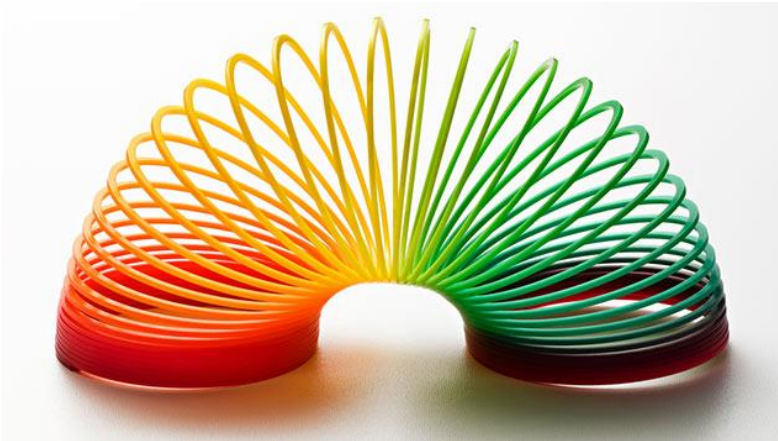


Netherlands Food and Consumer
Product Safety Authority
*Ministry of Agriculture,
Nature and Food Quality*

A flexible scope on phytosanitary diagnostics

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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

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

2. *Andean potato latent virus* (APLV)

3. *Phytophthora ramorum*

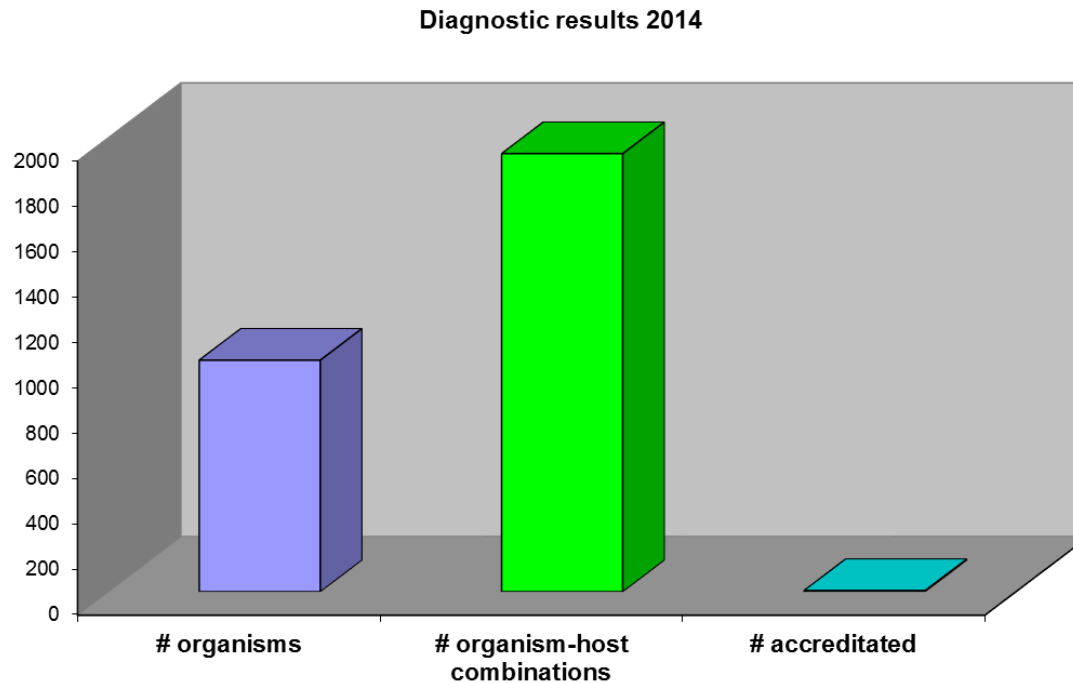
4. *Thrips palmi*

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

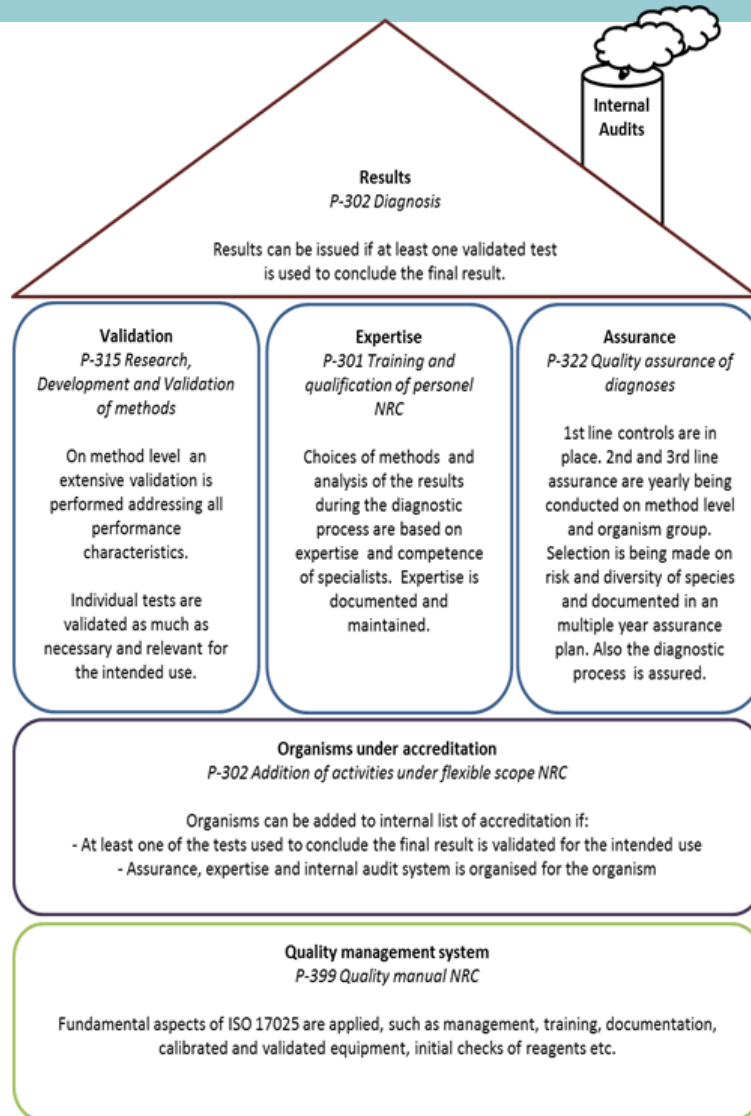
Fixed scope	Flexible scope
<ul style="list-style-type: none">- Process is fixed- Detailed description of type of test, organism(s) and matrix- Based on validation	<ul style="list-style-type: none">- Process is flexible- Generic description- Flexibility concerning object, or matrix or sample.- On-going validation



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

No	Material or product	Type and methods
1	Plant material and Arthropods	Identification of Arthropods using Morphology, Real-time PCR, PCR-Sequencing
2	Plant material and cultures	Identification of Plant pathogenic bacteria using Isolation, IF, Real-time PCR, PCR, Pathogenicity testing
3	Plant material and nematodes	Identification of Nematoda using Extraction, Morphology, Real-time PCR
4	Plant material and cultures	Identification of Oomycota using Isolation, Morphology, Real-time PCR
5	Plant material	Identification of plants using Morphology, PCR-Sequencing
6	Plant material	Identification of van plant viruses and viroids using Bioassay, DAS-ELISA, PCR, Real-time PCR, PCR-Sequencing





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





Preparation



Review

Adding to scope

Changing scope

Check

Approval

Approval

Addition to scope



- scope of accreditation of NRC



Adobe Acrobat
Document

- 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

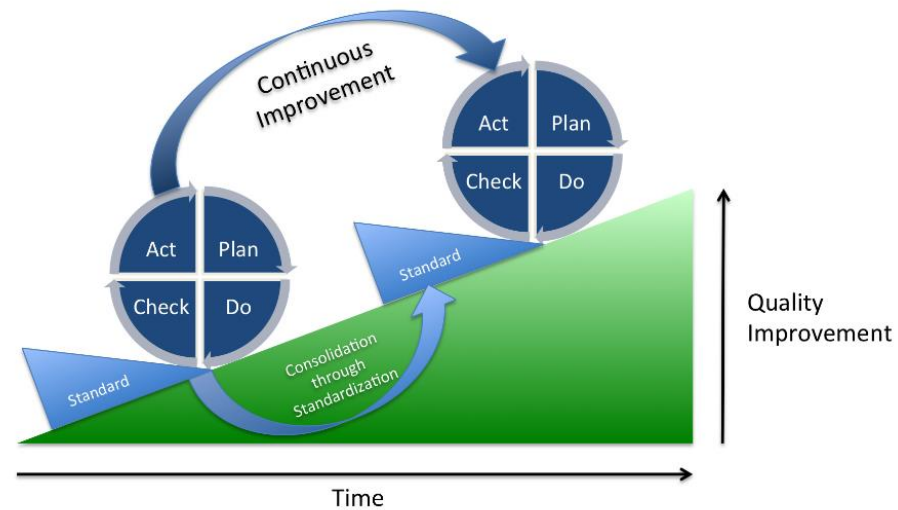
Genus	Species	Matrix	Bioassay	DAS-ELISA	PCR	Real-time PCR	PCR- Sequencing	Electron microscopy	r-PAGE	Date of addition
<i>Tymovirus</i>	<i>Andean potato latent virus</i>	leaves	TYMO_20160315_TPO	TYMO_20160315_ELISA	+		TYMO_20160315_SEQ	+		20160315
<i>Tymovirus</i>	<i>Andean potato mild mosaic virus</i>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

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:

van Leeuwen, G.C.M., Bosman, S., Souer, E., Edema, M.J., van der Blom, M. and Werkman, A.W. (2020), Implementation of an ISO 17025 flexible scope in the phytosanitary field at the National Reference Centre in the Netherlands. *EPPO Bulletin*, 00: 1– 8. <https://doi.org/10.1111/epp.12682>



Thank you for your attention

