Netherlands Food and Consumer
Product Safety Authority
Ministry of Economic Affairs

A phytosanitary focused flexible scope

The Dutch approach

Mariëtte Edema
NPPO
National Reference Centre (NRC)
The Netherlands

Outline

- Accreditation
- Why the search for phytosanitary based flex scope
- Ideas and requirements
- Follow-up

QUALITY MANAGEMENT SYSTEM

ISO 17025
ACCREDITED LABORATORY

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PM 7/84

Diagnostics
Diagnostic

Basic requirements for quality management in plant pest diagnosis laboratories

Bulletin OEPP/EPPO Bulletin (2014) **44** (2), 117–147

ISSN 0250-8052. DOI: 10.1111/epp.12118

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PM 7/98 (2)

Diagnostics
Diagnostic

PM 7/98 (2) Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity

Specific scope

This guideline includes specific quality management requirements for laboratories preparing for accreditation according to the ISO/IEC Standard 17025 *General requirements for the competence of testing and calibration laboratories* (references to relevant parts of ISO/IEC Standard 17025 are included). It should be noted that in EPPO standards the verb 'should' carries the highest level of obligation.

Specific approval and amendment

First approved in 2009–09.
Revision approved in 2014–04.

1. Introduction

Development of quality management systems (also referred to as management systems or quality systems)

2. Scope of accreditation: fixed scope and flexible scope

Historically, the accreditation of laboratories has usually

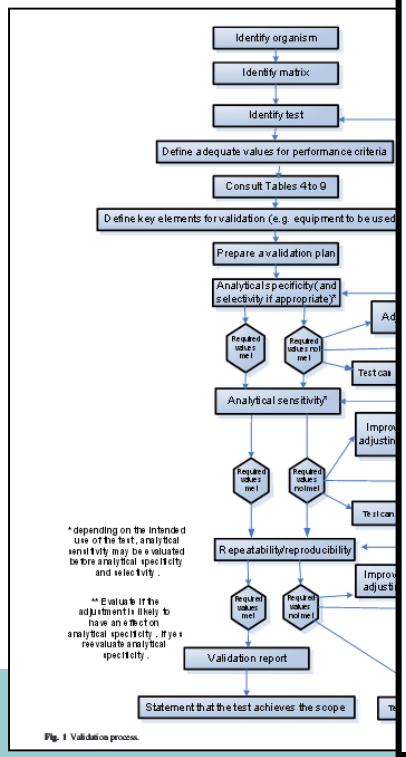


Fig. 1 Validation process.

Current accreditation NRC (17025 Fixed scope)

1	*Lycopersicon Esculentum* (tomato)	Isolation of *Clavibacter michiganensis subsp. michiganensis* in symptomatic material (stem) from tomato by plating on semi-selective media Identification of *Clavibacter michiganensis subsp. michiganensis* by IF, real-time PCR and pathogenity test	A-NRC-BAC-001

2 *Andean potato latent virus*

3 *Phytopthora ramorum*

4 *Thrips palmi*

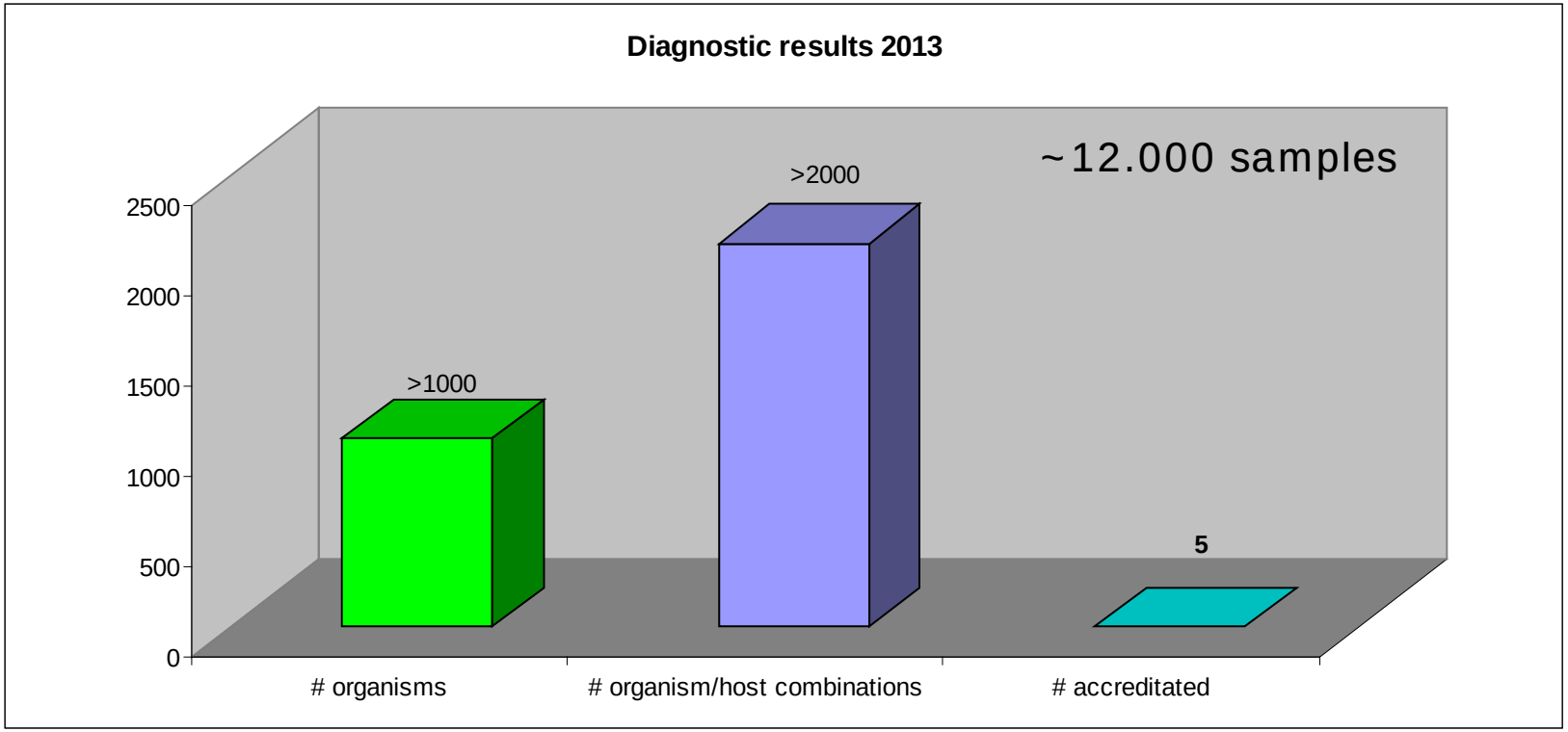
5 *Ditylenchus dipsaci*

Requirements for a fixed and standard flexible scope:

Each test:

- Extensive Validation or Verification
- 1st line controls
- 3rd line controls (or 2nd line)
- Management and technical requirements from ISO 17025 are fully applicable

Why the search for phytosanitary based flex scope



NRC is working since 2005 according to a quality system including audits on all processess, tests and diagnostic activities

Why the search for phytosanitary based flex scope

- Fixed/flex scope do not fit well with the nature of the work
  - » Some diagnoses are made only once every few years
  - » Diagnosis is based on knowledge and can be a combination of e.g. symptoms, literature, tests, morphology
- Extensive validation/verification and 2nd/3rd line controls for each single test perfomed is not possible

Conclusion:

Standard flexible/fixed scope not applicable

Phtosanitary based flex scope

Therefore:

- Agreement with Dutch Accreditation Board to come with a proposal for a specific scope

- Project started in January 2014

Phytosanitary based flex scope: diagnostic matrix

Diagnose-matrix

Organismegroep	Visual	Microscopie	Electron Microscopy	Extraction	Pathogenicity	Baiting	Indicator plants	Grafting	(non) selective isolation	Fatty acid	Isozym	r-Page	PCR	real-time PCR	Sequencen	ELISA	IF
Arthropoda	y	y											y	y	y		
Bacteria	y				y				y	n			y	y	y		y
Fungi en Oomycota	y	y		y		y			y				y	y	y	n	
Plantae	y	y											y	y	y		
Nematoda	y	y		y							n		y	y	y		
Viruses, viroids and phytoplasms	y		n				y	n				n	y	y	y	y	

No	Material or Product	Type	Methods
2	Plants, plant materials and cultures	identification of plant pathogenic bacteria	Visual, Pathogenicity, (non-) selective isolation, PCR, real-time PCR, Sequencing, IF

Assumptions for a Phytoflex scope

- Diagnostic process is the basis, not the test(s)
- Not all the tests mentioned in the scope need to be used in a diagnosis, decision by diagnostic specialist (traceable)
- Combination of tests used have to guarantee the quality of the diagnoses; at least one of the tests is validated
- Validation of tests: relevant performance criteria determined
- The accreditated diagnose can be applied to all (taxonomic) levels (family, genus, species, subspecies or pathovars)

titel	Overzicht organismen onder accreditatie							Pagina
code	R-VIR-000-001	versie 1	ingangsdatum:08-04-2015					

Acroniem	Species	Genus	TPO	DAS-ELISA	PCR	Sequentie	Enten	EM	R-PAGE
APLV	Andean potato latent virus	*Tymovirus*	x	x	x	x			
APMMV	Andean potato mild mosaic virus	*Tymovirus*	x	x	x	x			
APMoV	Andean potato mottle virus	*Comovirus*	x	x					
ArMV	Arabis mosaic virus	*Nepovirus*	x	x					
PVA	Potato virus A	*Potyvirus*	x	x	x				
PVY	Potato virus Y	*Potyvirus*	x	x	x				
PSTVd	Potato spindle tuber viroid	*Pospiviroid*			x	x			x
CSVd	Chrysanthemum stunt viroid	*Pospiviroid*			x	x			x
CEVd	Citrus exocortis viroid	*Pospiviroid*			x	x			x
CLVd	Columnea latent viroid	*Pospiviroid*			x	x			x
IrVd-1	Iresine viroid 1	*Pospiviroid*			x	x			x
PCFVd	Pepper chat fruit viroid	*Pospiviroid*			x	x			x
TASVd	Tomato apical stunt viroid	*Pos*							
TCDVd	Tomato chlorotic dwarf viroid	*Po*							
TPMVd	Tomato plant mancho viroid	*Po*							
DLVd	Dahlia latent viroid	*Ho*							
CIRV	Carnation Italian ringspot virus	*To*							
CBLV	Cucumber Bulgarian latent virus	*To*							
CymRSV	Cymbidium ringspot virus	*To*							
EMCV	Eggplant mottled crinkle virus	*Tom*							
GALV	Grapevine Algerian latent virus	*Tombusvirus*	x		x	x			
LFDV	Limonium flower distortion virus	*Tombusvirus*	x		x	x			
PetAMV	Petunia asteroid mosaic virus	*Tombusvirus*	x		x	x			
PepMV	Pepino mosaic virus	*Potexvirus*	x	x	x	x			
TRV	Tobacco rattle virus	*Tobravirus*	x		x				
SLRSV	Strawberry latent ringspot virus	*Unassigned*	x	x	x	x			
TRSV	Tobacco ringspot virus	*Nepovirus*	x	x	x	x			

Microbiological based

	methode opgenomen in accreditatie en voldoet aan eisen validatie en borging
	methode niet opgenomen in accreditatie, eventueel ondersteunend (geen validatie nodig)

	A	B	C	D	E	F	G	H	I	J	K
1	titel	Overzicht organismen	nder accreditatie mycologie						Pagina		
2	R-MYC-000-008		versie: 2			ingangsdatum		24-6-2015			
3											
4	**Overzicht organismen onder accreditatie Mycologie**										
5	**Groen: gevalideerde methode of valide literatuur volgens richtlijnen Eppo PM7/98**										
6	**Oranje: validatie nog niet afgerond, afgerond in augustus. Echter geen toets waarop de eindbepaling gebaseerd is.**										
7											
8											
9						Morfologische identificatie				Moleculaire techniek	
10		Literatuur									
11	ORGANISME	Literatuur tot 1990	Literatuur tot 7-4-2015	Literatuur	Visuele beoordeling symptoom	directe identificatie	(niet)selectieve Isolatie	Baiting	Extractie grond	(realtime) PCR	Sequentie
258	**Phoma medicaginis**		CMI 1503		x		x				
259	**Phoma pomorum**	Boerema et al	Boerema, 2004		x		x				
260	**Phoma tracheiphila**	Boerema et al.	EPPO PM 7/48(1), Boerema, 2004		x		x				
261	**Phoma tropica**	de Gruyter & Noordeloos 199	Boerema, 2004		x	x	x				
262	**Phomop**				x	x	x				
263	**Phomo**				x	x	x				
264	**Phomo**				x		x				
265	**Phomo**				x		x				
266	**Phragn**				x	x					
267	**Phragn**				x	x					
268	**Phragn**				x	x					
269	**Phragn**				x	x					
270	**Phyllac**		ear diseases, APS, 199		x	x	x				
271	**Phyllac**				x	x					
272	**Phyllos**				x	x	x				
273	**Phyllos**				x		x				
274	**Phyllosticta**				x		x			x	
275	**Phytophthora**	Erwin & Ribeiro, 1996			x	x	x	x		x	x
276	**Phytophthora alni**	Brasier et al, 2004. Myc. Res. 108: 1172-			x		x	x			x
277	**Phytophthora asparagi**	Saude & Hausbeck, Persoonia Volume 28, 2012, fungal Planet 110, 6 june 2012					x	x			x
278	**Phytophthora austrocedrae**	Hansen et al, Mycologia..			x		x	x			x
279	**Phytophthora cactorum**	CMI 111			x		x	x			x
280	**Phytophthora cambivora**	CMI 112			x		x	x			x
281	**Phytophthora capsici**	CMI 836			x		x	x			x
282	**Phytophthora cinnamomi**	CMI 113	EPPO concept 02 - 9748		x		x	x			x
283	**Phytophthora citricola**	CMI 114 ; Phytophthora citricola comple			x		x	x			x
284	**Phytophthora citrophthora**	CMI 33; Waterhouse 1970			x		x	x			x
285	**Phytophthora cryptogea**	CMI 592			x		x	x			x
286	**Phytophthora erythroseptica**	CMI 593			x		x	x			x
287	**Phytophthora fragariae**	Waterhouse 1970; Erwin & Ribeiro 1996			x	x	x	x			

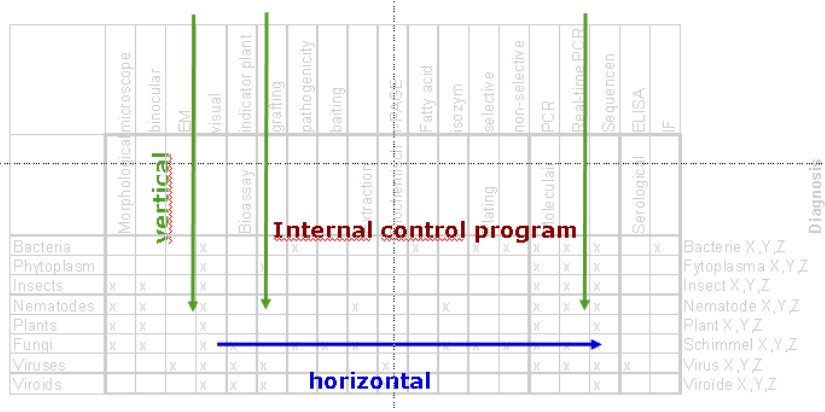
Morphological based

Requirements for a Phytoflex scope

In a Phytoflex scope the diagnostic process is the object of accreditation i.o. tests or methods:

Requirements:

- Quality management system is applicable for all diagnoses
- Competence of diagnostician – Expertise Document
- Verification of tests
- Use of quality controls and assurance



Assuring the quality

- Vertical assurance (1st/2nd/3rd line)
  - Each test relevant 1st line controls
  - 2nd (blind samples) and 3rd line controls (PT) at method level

- Horizontal assurance
  - Individual diagnoses: combination of tests, multiple assessors or second opinion
  - Diagnostic process
    - ‘blind’ diagnostic samples throughout the whole process
    - Exhange of samples with external diagnosticians including discussion on the followed route

Addition of new organisms

		minimal demands:						
Situation	**example**	**Full validation**	**Validation as appropriate**	**1st line control**	**2nd/3rd line controls**	**internal audiit**	**Approval by HoL**	**report to AB**
addition of a new method	Malditov	y		y	y	y	y	y
addition of a new organism group	Mollusca	y		y	y	y	y	y
addition of a new test in existing method	primers x/y in real-time PCR		y	y	tbd	tbd	y	n
addition of a new organism in existing method/organism group	Potato virus X with real-time PCR		y	y	tbd	tbd	y	n

Follow-up

- End of October 2015 audit on flexible scope by Dutch Accreditation Council

- EPPO EWG on flexible scope

Influence on quality of the work