



Netherlands Food and Consumer  
Product Safety Authority  
*Ministry of Economic Affairs*



## A flexible scope on phytosanitary diagnostics

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**Diagnostics**  
**Diagnostic**

**Basic requirements for quality management in plant pest diagnosis laboratories**

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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

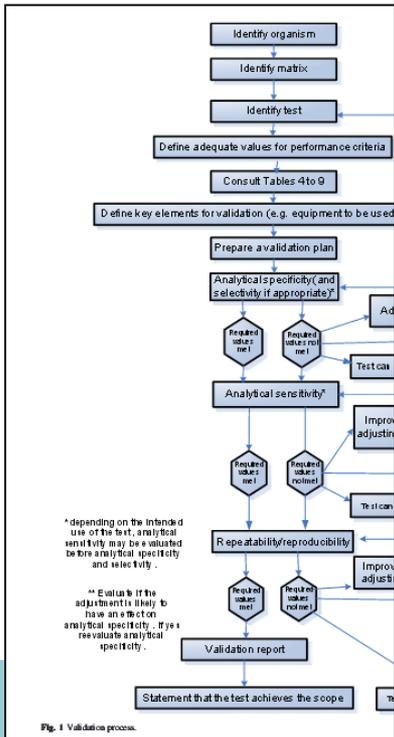


Fig. 1. Validation process.

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## Current accreditation NRC (17025 Fixed scope)

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	A- NRC- BAC- 001
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2 *Andean potato latent virus*

3 *Phytophthora ramorum*

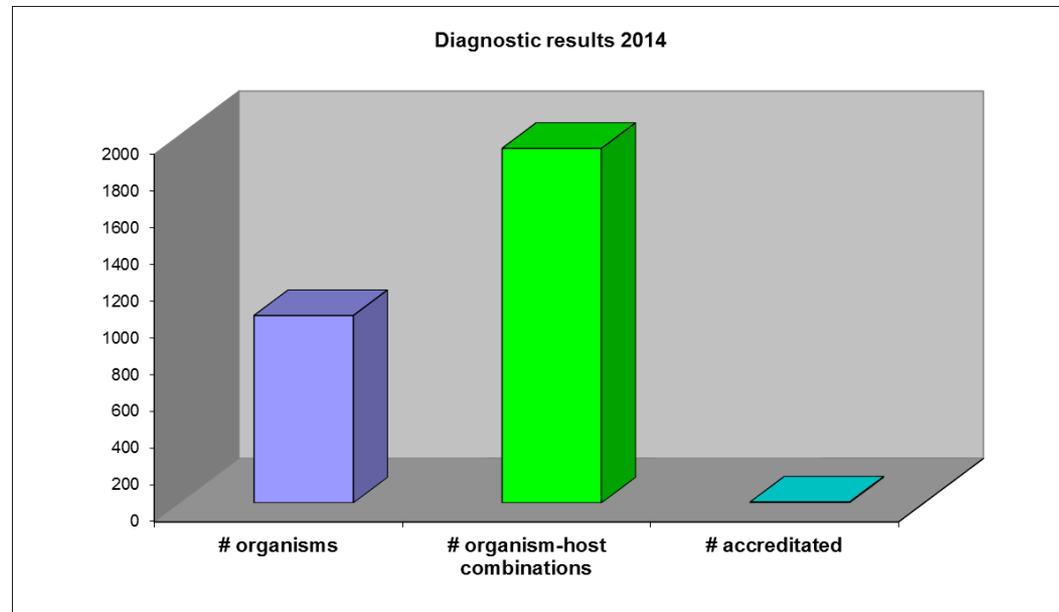
4 *Thrips palmi*

5 *Ditylenchus dipsaci*





# Why the search for phytosanitary based flexible scope



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



## Why the search for phytosanitary based flexible scope (2)

- Standard Fixed/flex scope do not fit well with the nature of the work
  - » Some diagnoses/tests are performed only once every few years
  - » Diagnostic process is based on knowledge and can be a combination of e.g. symptoms, literature, tests, morphology
- Extensive validation and 2<sup>nd</sup>/3<sup>rd</sup> line controls for each single test performed: not feasible



## Phytosanitary based flex scope

Therefore:

- Agreement with Dutch Accreditation Council to come with a proposal for an specific scope
- Project started in the end of 2013
- Audit in October 2015



# Principles flex scope NRC



Method: e.g. DAS-ELISA, PCR, morphology

Test: application method to a specific pest (antisera, primers)

Diagnose  $\neq$  diagnosis of new or unknown pests



## 1) Scope of accreditation

In our work the diagnostic process is leading i.o. tests

- Quality management system is applicable for all tests/diagnoses
- Methods are extensive validated, tests fit for purpose
- Use of quality controls and assurance is method based
- Competence of diagnostician – Expertise Document



# 1) Scope of accreditation

Diagnostic matrix

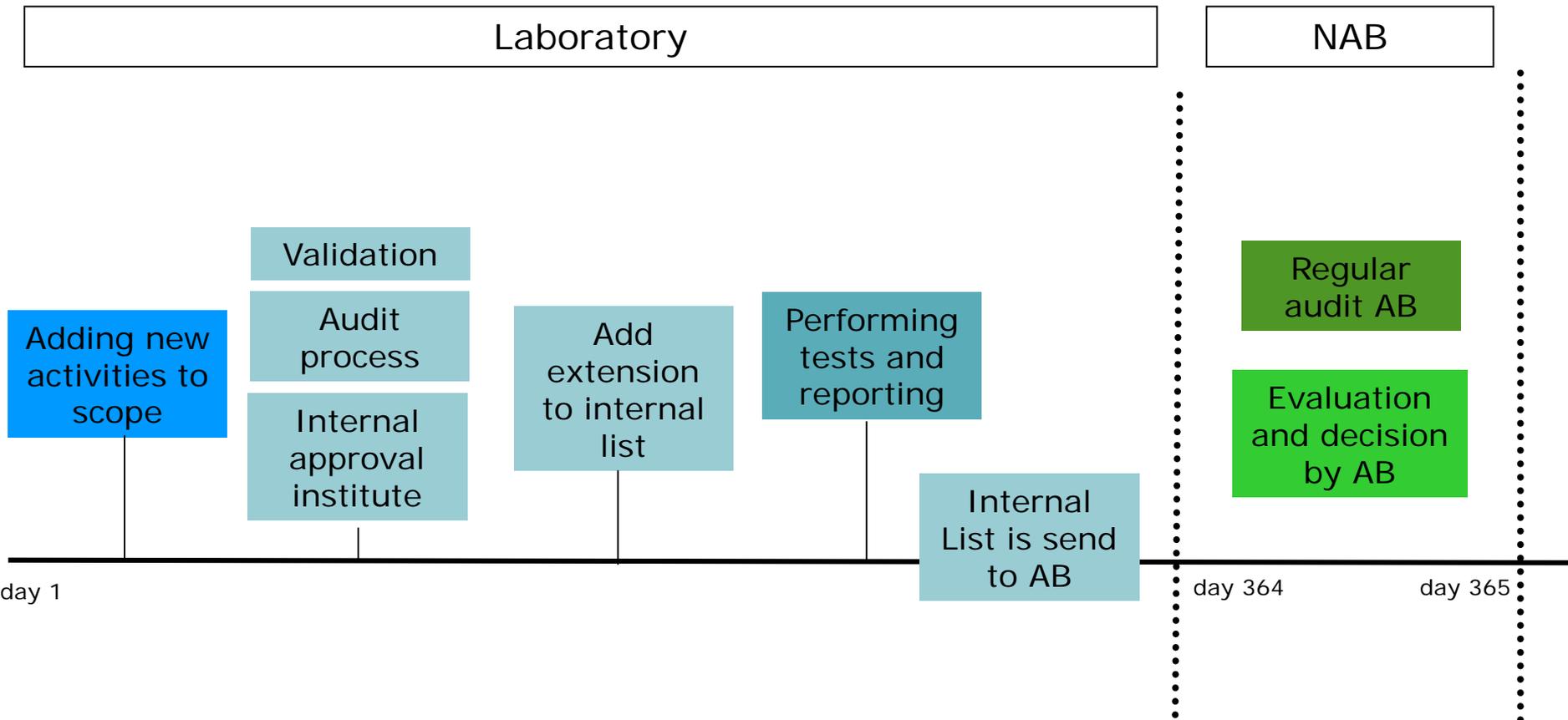
Organism group	Visual	Microscopy (morphological)	Electron microscopy	Extraction	Pathogenicity	Baiting	Indicator plants	Grafting	(non-) selective isolation	Fatty acid	Isozym analysis	r-Page	PCR	real-time PCR	Sequencing	ELISA	IF
Arthropoda	x	x											x	x	x		
Bacteria	x				x				x	x			x	x	x		x
Fungi en Oomycota	x	x		x		x			x				x	x	x	x	
Plantae	x	x											x	x	x		
Nematodes	x	x		x							x		x	x	x		
Viruses, viroids and phytoplasts	x		x				x	x				x	x	x	x	x	



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



## 2) Management of scope

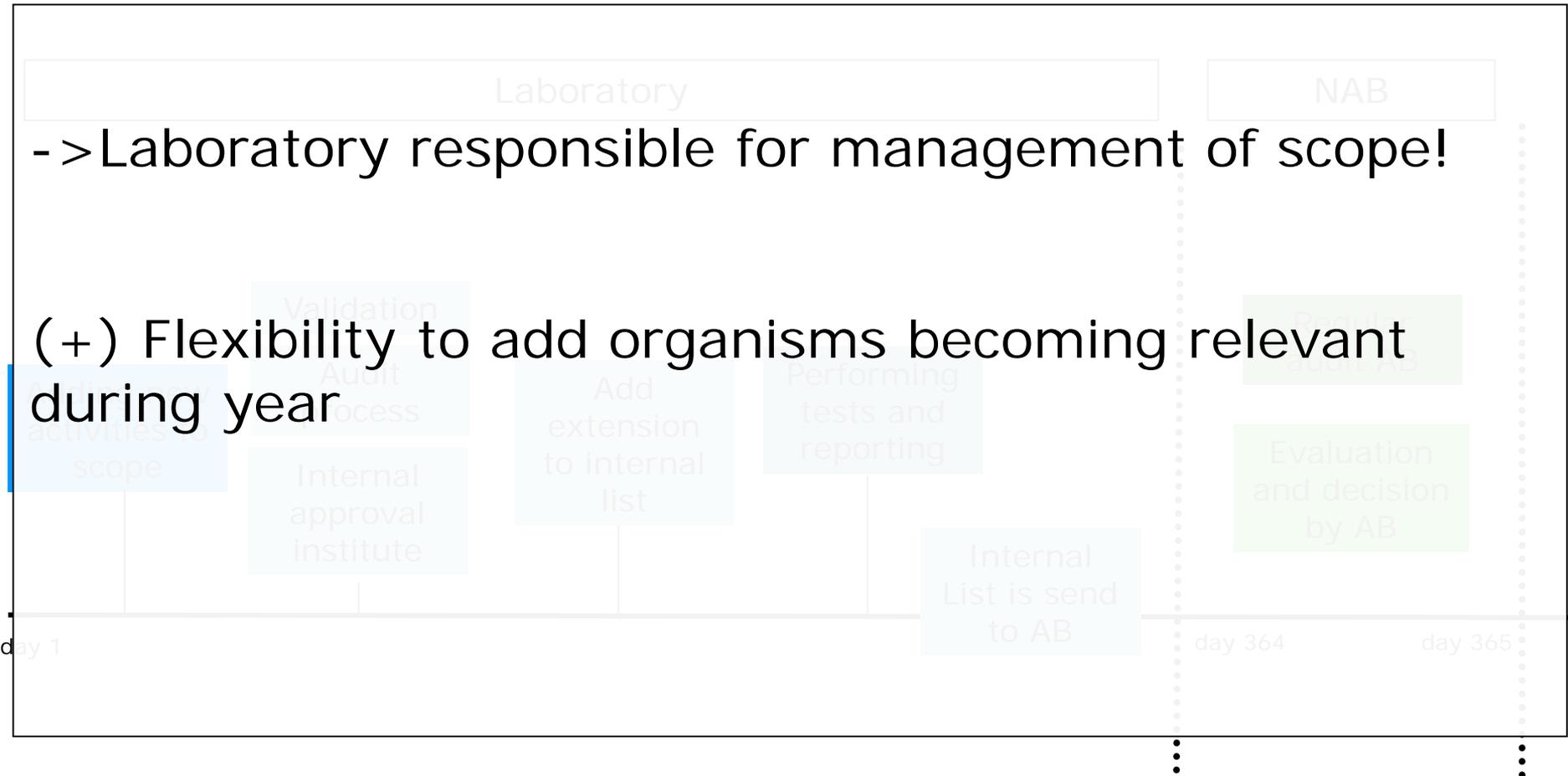




## 2) Management of scope

-> Laboratory responsible for management of scope!

(+) Flexibility to add organisms becoming relevant during year





### 3) Internal list

- Not all tests mentioned in the scope need to be used in each identification, decision by diagnostic specialist (traceable)
- Combination of tests used guarantee the quality of the diagnoses; at least one of the tests is validated
- Validation/verification of tests: relevant performance criteria determined (fit for purpose)



### 3) Internal list (example)

Order	Taxon	Stadium	Morphological	PCR	Sequence analysis	Date
Thysanoptera	<i>Thrips palmi</i>	all stadia	THRPL_20151008_MOR	THRPL_20151008_PCR	THRPL_20151008_SEQ	20151008
Lepidoptera	<i>Spodoptera</i>	Adult; egg	SPODG_20151008_MOR			20151008
Lepidoptera	<i>Spodoptera eridania</i>	all stadia	SPODG_20151008_MOR	SPODG_20151008_PCR	SPODG_20151008_SEQ	20151008
Lepidoptera	<i>Spodoptera frugiperda</i>	all stadia	SPODG_20151008_MOR	SPODG_20151008_PCR	SPODG_20151008_SEQ	20151008
Lepidoptera	<i>Spodoptera littoralis</i>	all stadia	SPODG_20151008_MOR	SPODG_20151008_PCR	SPODG_20151008_SEQ	20151008
Lepidoptera	<i>Spodoptera litura</i>	all stadia	SPODG_20151008_MOR	SPODG_20151008_PCR	SPODG_20151008_SEQ	20151008
Coleoptera	<i>Monochamus galloprovincialis</i>	Adult	MONCGA_20151008_MOR		MONCGA_20151008_SEQ	20151008



## 4) Assuring the quality

- Method focussed assurance (1st/2nd/3rd line)
  - Each test relevant 1st line controls
  - 2nd (blind samples) and 3rd line controls (Proficiency Testing) at method level
- Process focussed assurance
  - Individual diagnoses: combination of tests, multiple assessors or second opinion
  - Diagnostic process
    - › ‘blind’ samples throughout the whole process

Quality assurance of low or infrequent #samples: possible



## Procedure for addition of new organisms/tests

Situation	example	minimal demands:					internal audit	Approval by Head of Lab	Preliminary approval by AB
		Full validation	Validation fit for purpose	1st line control	2nd/3rd line controls				
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	



## End of October 2015: audit on flexible scope

### A) Reassessment Fixed scope

-> no major remarks

### B) Audit new Flexible scope

- > best solution for our work
- > morphological analysis
- > scope/format internal list
- > validation & internal audit



# Experiences

