



**ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA  
PROTECTION DES PLANTES  
EUROPEAN AND MEDITERRANEAN PLANT PROTECTION  
ORGANIZATION**

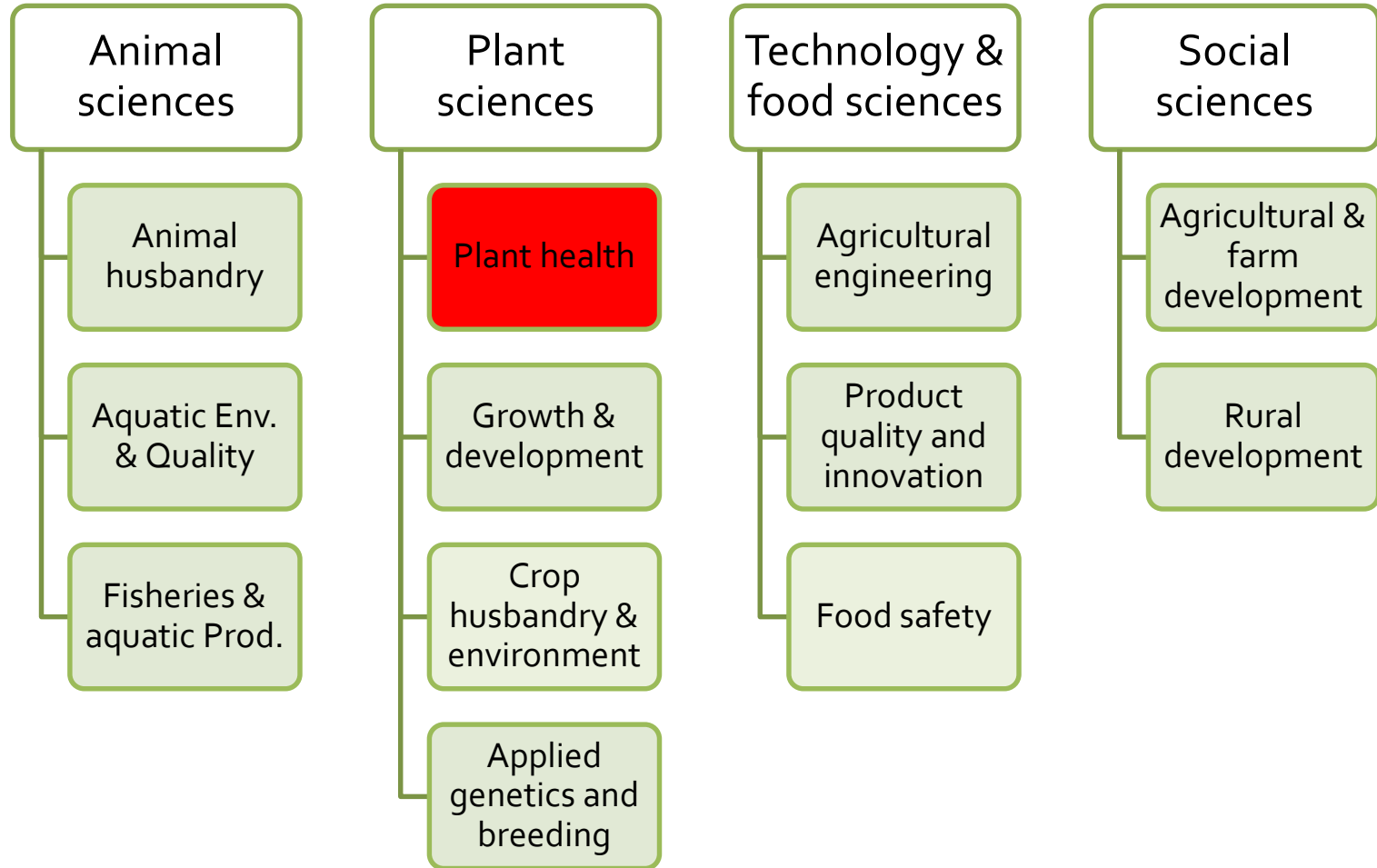
**Workshop on Flexible Scope**

**The ILVO experience**

Flanders research institute for  
agriculture, fisheries and food

Kris De Jonghe

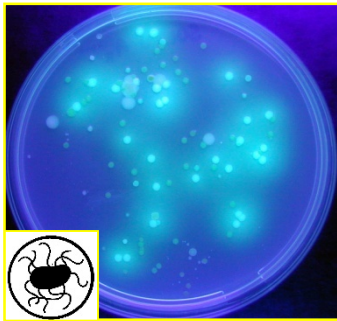
Wageningen, June 26-28, 2017



# Diagnostic Centre for Plants – General structure

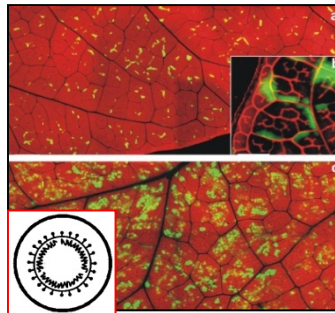
Detection of quarantine and regulated organisms ( → NPPO)

Diagnostics for professional growers, field research stations, extension workers, managers of forests & (open) green spaces, private persons, etc.



## Bacteriology

Johan Van Vaerenbergh



## Virology & phytoplasmology

Kris De Jonghe



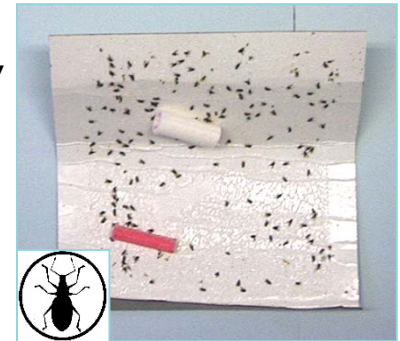
## Mycology

Kurt Heungens



## Entomology & Acarology

Hans Casteels



## Nematology

Nicole Viaene

Scientific Director  
Quality Manager

Martine Maes  
Annemie Hoedekie (ass. Sven Inghelbrecht)

# Diagnostic Centre for Plants – Quality management

## ISO 17025 accreditation:



In addition also certified for  
environmental management (ISO14001) :



**CERTIFICAAT**

EN ISO 14001 : 2004  
Milieumanagementsysteem

# ISO 17025 Accreditation

## 15 matrix/test combinations + flex scope

Matrix	Gemeten eigenschap	Beschrijving beproevingsmethode	Interne testcode
<b>ENTOMOLOGIE (Hans Casteels)</b>			
Planten	Aantonen van adulte stadium van Thrips palmi	EPPO Diagnostic protocol PM 7/3 (1) [EPPO Bulletin 31(2001), 53-60] Isolatie met Berlese-trechter Morfologische identificatie met binoculair/microscoop	W03101
Planten	Aantonen van tweede larven stadium Thrips palmi	Masahisa Miyazaki & Iwao Kuda, 1986. Descriptions of Thrips larvae which are noteworthy on cultivated plants (Thysanoptera: Thripidae). Akitu ISSN 0389-2751 New Series Isolatie met Berlese-trechter Morfologische identificatie met binoculair/microscoop	W03101
Feromoonvallen	Aantonen van adulte stadium van Diabrotica virgifera	EPPO Diagnostic protocol PM 7/36 (1) [EPPO Bulletin 34 (2004), 289-293] Detectie met rasterwerk 'Diabrotica' Morfologische identificatie met binoculair	W03104

# ISO 17025 Accreditation

## 15 matrix/test combinations + flex scope

Matrix	Gemeten eigenschap	Beschrijving beproevingsmethode	Interne testcode
<b>MYCOLOGIE (Kurt Heungens)</b>			
Planten	Aantonen van Phytophthora ramorum	EPPO Diagnostic protocol PM 7/66 (1) [EPPO Bulletin 36 (2006),145-155 ] Isolatie en morfologische identificatie d.m.v. uitplating en microscopie.	W03S03
Planten	Aantonen van Phytophthora kernoviae	Brasier CM, Beales PA, Kirk SA, Denman S, Rose J (2005) Phytophthora kernoviae sp. nov., an invasive pathogen causing bleeding stem lesions on forest trees and foliar necrosis of ornamentals in Britain. Mycological Research 109(8), 853-859 Isolatie en morfologische identificatie d.m.v. uitplating en microscopie	W03S04
Planten	Aantonen van Phytophthora kernoviae	EPPO Diagnostic Protocol 7/112 (1) {EPPO Bulletin 43 (2013), 81-93} Isolatie en morfologische identificatie d.m.v. uitplating en microscopie	W03S04

# ISO 17025 Accreditation

## 15 matrix/test combinations + flex scope

### BACTERIOLOGIE (Johan Van Vaerenbergh)

Aardappelknollen	Aantonen van afwezigheid of vermoedelijke aanwezigheid van <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i>	Richtlijn 2006/56/EG, Bijlage I (zonder confirmatie)	
		Monstervoorbereiding	W03B03
		Detectie d.m.v. immunofluorescentie microscopie	W03B04
		Detectie d.m.v. PCR	W03B05
Aardappelknollen	Aantonen van afwezigheid of vermoedelijke aanwezigheid van <i>Ralstonia solanacearum</i>	Richtlijn 2006/63/EG, Bijlage II (zonder confirmatie)	
		Monstervoorbereiding	W03B03
		Detectie d.m.v. selectieve isolatie	W03B09
Oppervlaktewater	Aantonen van afwezigheid of vermoedelijke aanwezigheid van <i>Ralstonia solanacearum</i>	Richtlijn 2006/63/EG, Bijlage II	
		Monstervoorbereiding en detectie d.m.v. selectieve isolatie	W03B14

### NEMATOLOGIE (Nicole Viaene)

Aardappelknollen Plantenwortels Grond	Aantonen van <i>Meloidogyne</i> spp.	EPPO Diagnostic protocol PM7/41(2) [EPPO Bulletin 39 (2009 ),5-17] Extractie van vrijlevende nematoden met automatische zonale centrifuge (AZC) Detectie en identificatie d.m.v. microscopische analyse	W03N08
Nematoden	Moleculaire soortbepaling <i>Meloidogyne chitwoodi</i> , <i>M. fallax</i> en <i>M. hapla</i>	EPPO Diagnostic protocol PM7/41(2) [EPPO Bulletin 39 (2009 ),5-17] ; Moleculaire identificatie met PCR	W03N10

# ISO 17025 Accreditation

## 15 matrix/test combinations + flex scope

### VIROLOGY (Kris De Jonghe)

Matrix	Parameter	Method	Internal code
Plants and multiplication material (*)	Screening for the absence or suspected presence of plant viruses	ELISA method	W03V09
Plants and multiplication material (*)	Detection of plant pathogenic viroids, viruses and 'Candidatus Liberibacter' by means of sequence-specific probe based real-time (RT-)PCR (general procedure).	q(RT-)PCR methode	W03V10

### (\*) Flexibele scope

In the framework of his accreditation, the laboratory has the permission to determine all parameters belonging to the group (of parameters) listed in the second column for the corresponding matrices belonging to the group (of matrices) mentioned in the first column. This permission is given provided that an appropriate validation is performed in accordance with the global validation concept as stipulated in the quality system of the laboratory. At any time, and at the request of any applicant, the laboratory keeps an updated list of the specific parameters and matrices covered by the above description.

Scope: general description focussing on the method. However:

Three additional documents, linked to W03V09 and W03V10:

1. List of organism/matrix combinations in the flex scope (ELISA and qPCR)
2. Respective decision schemes
3. Specific requirements for each of the organism/matrix combinations



# Flex scope @ ILVO

**Aim:** Offer quality, assure traceability & organisation, meeting client demand

ISO 17025 standard

**Starting point:** fixed scope on a variety of method/organism/matrix combinations (since 2008)

**Question:** How to move towards more flexibility ?

**Implication:** Move from more control to more trust

**Problem:** General flexible scope “Diagnosis of plant pathogens” and staying within the boundaries of the ISO 17025 is not possible

*constraints:* level of validation, “measure” expertise, availability of ref. material, use of controls (spec. samples of unknown ethiology)

# Flex scope @ ILVO

ILVO choice: Flexibility created around generally accepted methods

Real-time PCR

ELISA

- Supported by international standards (EPPO)
- Supported by TPS results (EPPO, ERA-net projects, EU projects, etc.)
- Still a high level of control (“fixed parameters”) on results leaving the lab under the scope:
  - ✓ No freedom of choice to include non controlled methods (not lab validated methods)
  - ✓ Never deviate from lab validated protocols, irrespective of the experts’ judgement
  - ✓ Specific procedure to be followed when the lab wants to include new targets, new matrices, new strains, etc. in the scope. (“Procedure introduction of a new....”)
  - ✓ Always perform an additional lab validation, on key parameters + literature information (sampling, LOD, specificity, accuracy, etc) – less burden on repeatability, reproducibility, robustness
  - ✓ Strict rules on internal Quality assurance (1/2/3 line controls (incl. PTs), internal audits, traceability, etc.)
- However: no immediate need to have an external audit first, before these additions can be added to the scope (trust)

# Flex scope @ ILVO

## ISO 17025 limitations for a broad Plant Health diagnosis scope

- How to include the expertise of the diagnostician & diagnosis aspects ?

Split the decision process and the wet lab activities in

- **pre-analysis** (expertise, drafting of a decision tree) and
- **actual analysis in the lab**

*Organise around groups of methods*

(tests for organism/matrix combinations = analytical flex scope as currently applicable within the ISO17025 boundaries) ??

*Assess and fix the level of validation for each test based on Risk Analysis*

Alternative ....

New separate quality label for Plant Health laboratories of excellence in addition to the analytical flex scope (ISO 17025) ?



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