Implementation of ISO/IEC 17025 2017 at National Institute of Biology (NIB)

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4th EPPO Workshop for Heads of Plant Pest Diagnostic Labs

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Introduction

- **National Institute of Biology (NIB),** independent Public Research Institution for Life Sciences in Slovenia, established in 1960 (http://www.nib.si/eng/, above 140 employees in 4 research departments).
- **FITO - Department of Biotechnology and Systems Biology,** the largest department of NIB (4 working units, 3 diagnostic labs, currently 58 employees)
  - **National Reference Laboratory** for plant pests, phytoplasmas, viruses and bacteria
  - **Partner of EURL** for:
    - bacteria
    - viruses, viroids and phytoplasmas
  - **Development of new detection tests and methods**, qPCR, dPCR


Plant Pathology (2017) Doi: 10.1111/ppa.1

Filling the gaps in diagnostics of *Pepino mosaic virus* and *Potato spindle tuber viroid* in water and tomato seeds and leaves

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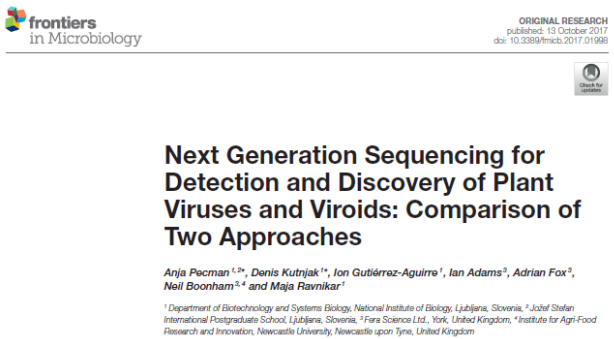
frontiers in Microbiology

ORIGINAL RESEARCH published: 13 October 2017 doi: 10.3389/fmicb.2017.01998

Next Generation Sequencing for Detection and Discovery of Plant Viruses and Viroids: Comparison of Two Approaches

Anja Pecman[1,2], Denis Kutnjak[1*], Ion Gutiérrez-Aguirre[1], Ian Adams[3], Adrian Fox[3], Neil Boonham[3,4] and Maja Ravnikar[1]*

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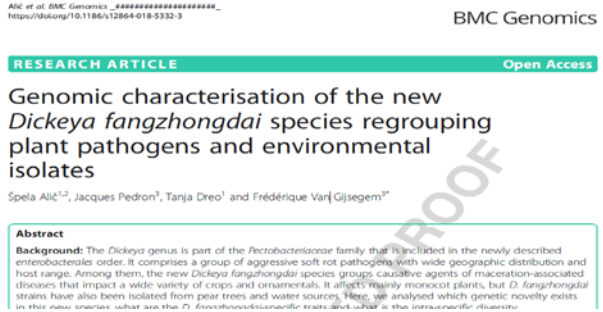

Alić et al. BMC Genomics _____ https://doi.org/10.1186/s12864-018-5332-3

BMC Genomics

RESEARCH ARTICLE Open Access

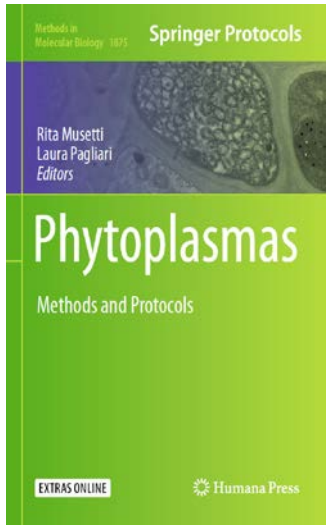
Genomic characterisation of the new *Dickeya fangzhongdai* species regrouping plant pathogens and environmental isolates

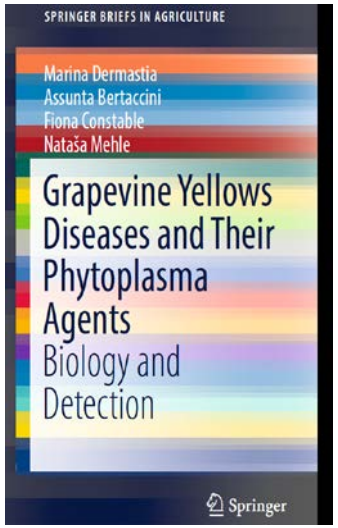
Špela Alić[1,2], Jacques Pedron[3], Tanja Dreo[1] and Frédérique Van Gijsegem[3*]

PROOF

Abstract

Background: The *Dickeya* genus is part of the *Pectobacteriaceae* family that is included in the newly described *enterobacterales* order. It comprises a group of aggressive soft rot pathogens with wide geographic distribution and host range. Among them, the new *Dickeya fangzhongdai* species groups causative agents of maceration-associated diseases that impact a wide variety of crops and ornamentals. It affects mainly monocot plants, but *D. fangzhongdai* strains have also been isolated from pear trees and water sources. Here, we analysed which genetic novelty exists in this new species, what are the *D. fangzhongdai*-specific traits and what is the intra-specific diversity





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Introduction

- **Organizers of proficiency tests** on bacteria, viruses and phytoplasmas starting in 2015, thereafter organized yearly with increasing number of participants worldwide (2018, 45 participants, 26 counties, three continents)
- **Characterization of reference materials** for GMOs and plant pests
- **Trainings on GMOs and plant pest diagnostic** for international participants, etc.

PT	Plant pest	Number of participant (number of countries)	
2015_01	*R. solanacearum*	18 (16)	
	E. amylovora	17 (16)	
2016_01	*R. solanacearum*	2 (2)	
2016_02	*phytoplasma (FD / BN)*	17 (16)	
	X. fastidiosa	29 (22)	
	‚Ca. L. solanacearum‘	20 (15)	
2017_01	*E. stewartii*	20 (14)	
	RSSC (detection & phylotyping)	29 (21)	
	phytoplasma (AP, ESFY, PD)	23 (16)	
2017_02	*phytoplasma (FD / BN)*	1 (1)	
2018_01	*RSSC*	29 (19)	
	E. amylovora	27 (19)	
	TSWV/INSV/CSNV	4 (4) / 18 (14)	
2018_02	*Small ILC on detection of Cms DNA*	2 (2)	

Valitest

Validation of diagnostic tools for animal and crop – Resilient and resource efficient value chains (GA No. 773139)

Valitest EU Project @ValitestProject · Apr 9

TPS starting!samples and reagents for the TPSs on Erwinia amylovora (fire blight) are already with most participants. impressive figures below
6 tests (real-time PCR, LFDs and LAMP)
32 participants
20 different countries
46 panels of samples
920 samples
thanks to @NIB_FITO_SI

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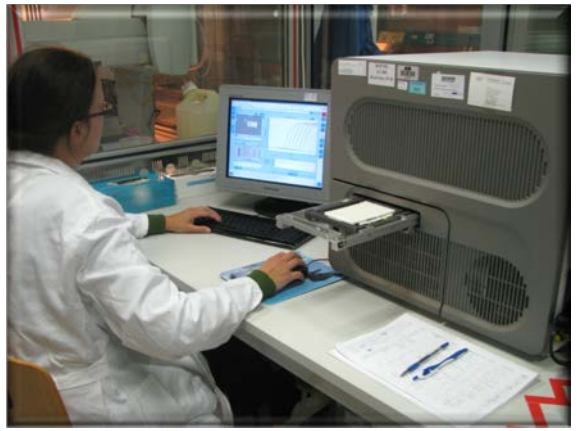
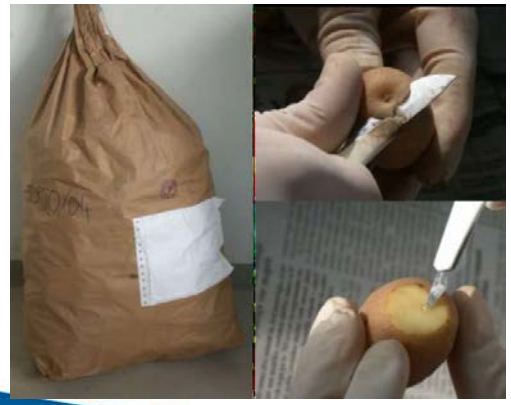
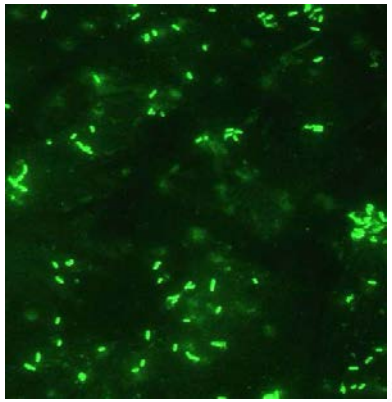
Quality management system and accreditation based on ISO/IEC 17025



- **Beginnings of QMS in plant pest diagnostic activity in 1997**
- **NIB obtained ISO 9001 certificate in 2004**
- **GMO detection accredited in 2003; since 2006 - flexible scope of accreditation**
- **Detection of microorganisms – plant pathogens, flexible scope**
  - detection of phytoplasmas accredited in 2012
  - detection of bacteria accredited in 2018
  - **accreditation scopes:** Annex to the accreditation certificate (LP-028) and in the List of accredited methods for detection of GMOs and microorganisms – plant pathogens on the web site of Slovenian accreditation http://www.slo-akreditacija.si/acreditation/nacionalni-institut-za-biologijo/





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General NIB/FITO approach to implementation of ISO/IEC 17025:2017

- The majority of new requirement were already implemented in QMS, including risks and opportunities, however some of them have to be additionally clarified or documented
- To implement new requirements to upgrade and improve QMS with changes which will

  improve QMS the system without too many changes

Implementation of new requirements of ISO/IEC 17025:2017 in QMS of NIB, FITO

Main phases of implementation:

- studying the changes of the new standard, beginning of 2018
- presentation of new requirement to employees
- preparation of the implementation plan
- coordination / harmonization of changes between diagnostic labs, define final changes of the QMS documentation
- gradual implementation of changes (adaptation of existing documents, adoption of changes in practice, first documents changed in 2018)
- internal audits performed in spring 2019 according to ISO/IEC 17025:2017
- final approval of QMS by National Accreditation Body (in November 2019)

Figure 1. *Corylus avellana* with (a) dead branches, (b) a tree with unusual proliferation of thin twigs that were infected with 'Candidatus Phytoplasma fragariae', and (c) a healthy tree.

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change in the standard	Solution at NIB, FITO	New / updated documents
4 General requirements				
4.1	impartiality	clarifying **and risks identification**	**risk analysis performed** including but not limited to: management, ownership, personnel, customers, etc.	**Document on risk analysis; Confidentiality statement**
4.2	confidentiality	clarifying (customer should be informed in advance about intends to make information publicly available)	risk analysis performed;	**Document on risk analysis; Quality manual**
5 Structural requirements				
5.3	range of lab activities	lab activities have to be defined and documented	lab activities defined in list of accredited methods, regularly updated because of flexible scope	/
5.6	personnel and other resources	organizational changes – quality / technical manager and deputies not necessary	functions still exists, therefore no changes were implemented	/

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / updated documents
6 Resource requirements				
6.2	personnel	- competence requirements for each function has to be **defined and monitored,** - personnel **shall act impartially**	- competence requirements for some key functions e.g. responsible analyst updated; - **monitoring already performed**: regular meetings, internal audits, annual personal reports, proficiency tests, blind samples, etc.; - **text on impartiality prepared**, - importance of impartial work presented to employees	**Quality manual;** **Confidentiality statement**
6.4	equipment	- **equipment extended** to reagents measurement standards, RMs, software, consumables, etc.; - reference to ISO 17034 for RM producers	- control system for key reagents, standards, RMs, software already in place**,** **- the definition of equipment updated** including also the reference to ISO 17034	**Quality manual;** **Document on equipment control**
6.5	metrological traceability	lab shall establish metrological traceability of **measurement results**	- already established – when possible equipment **calibration is provided by accredited calibration labs**; - RMs are provided from competent producers (when available), the text clarified	**Quality manual;** **Document on equipment control**

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / updated documents
7 Process requirements				
7.1	review of requests, tenders, contracts and subcontracts	- deviations requested by the customer **shell not impact the integrity** of the lab or the validity of results	- **text on maintaining the integrity added**	**Document on review of contracts**
7.2	methods - selection, verification, validation	the concept of "**method verification**" is introduced	the concept of **verification already introduced** and verifications performed	/
7.3	sampling	sampling highlighted as a lab activity as testing and calibration	not relevant for NIB	/
7.4	handling of samples	when the customer requires to perform a test despite **the deviation**, the lab shall **indicate in the report** which results may be affected	**the text on reporting was clarified and updated**	**Document on control of records and reporting**
7.6	measurem. uncertainty (MU)	new terminology **– evaluating MU instead of estimation of MU**	critical factors influencing MU are already defined and controlled, described in QMS document and published (Mehle et al., **EPPO Bulletin** 44 (3), 2014)	/

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
7.7	ensuring the validity of results	- **extended list for monitoring the validity of results**; - **PT providers that meet the ISO/IEC 17043** requirements are competent	**updated text on monitoring the validity of results**, although the majority of monitoring activities was already performed (use of RMs when available, participation in PTs, checks of equipment, replicate tests, retesting retained samples, blind samples, etc.)	**Quality manual**
7.8	reporting	- the **results shall be reviewed and authorized**; - data provided by a customer shall be clearly identified; - when lab isn‘t responsible for sampling it shall be stated in the report that the **results refer only to the received samples** which have been tested	- **updated and clarified text on the reporting**, - **updated Report**	**Document on control of records and reporting;** **Report**
7.9.	complaints	- **handling process for complaints shall be available** to interested parties; - when possible **the complaint shall be handled by person not involved in the lab activities** in question	**complaint handling procedure was updated**	**Document on control of actions, complaints and improvements**
7.10	nonconfor ming work	- **consideration of risks** - actions based upon the risk levels established by the laboratory	**risks included** in the nonconformance handling procedure	**Quality manual; Document on control of actions, complaints and improvements; Document on control of nonconformances; Form for nonconformances**

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
7.11	control of data and information management	- requirements **adapted to computerized lab information management systems**; - external provider of the system that meets all applicable requirements of ISO/IEC 17025 is competent	all QMS documents, key data and information are in paper versions;	/
8 Management system requirements				
8.1	options A, B	- **A - QMS established according to ISO/IEC 17025**, clauses 8.2-8.9 **- B - QMS is established according to ISO 9001**, In both options fulfillment of the clauses 4-7 of ISO/IEC 17025 are necessary	**option** A and ISO 9001	/
8.2-8.4	management system documentation, control of documents and records	- no significant change; - quality manual and quality politic were withdrawn	no changes were implemented	/

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / updated documents
8.5	**actions to address risks and opportunities**	lab **shell consider the risks and opportunities (R&O)** to: - achieve intended results - enhance opportunities to achieve the purpose and objectives - prevent, reduce undesired impacts and failures - achieve improvements, lab shall plan: - actions to address this R&O - How to integrate and implement these actions to QMS - Evaluate the effectiveness	**the basic approach on R&O management used for years** in FITO (also summarized in management review in 2018): - **FITO has been focused on identifying R&O and minimize risks and maximize opportunities for years** (positive business results, projects, new customers, increasing number of employees…) - **during implementation, upgrades and improvements of QMS risks were systematically minimized** (e.g. regular trainings of personnel, deputies for key staff, cooperation in PTs, internal audits, management of equipment, detailed process of introduction of new methods with validation procedure, etc.); - **R&O are discussed and identified during meetings of senior staff and internal audits**; - **critical factors with possible impact on the results are defined, controlled and described in QMS document** (Mehle et al., **EPPO Bulletin** 44 (3), 2014. The document has to be fulfilled in validation process before accreditation of a new method; - additionally the **R&O identification table was introduced** and is fulfilled regularly on meetings of senior staff; - additionally the **process of risk management will be described**	**Quality manual;** **Table on risks;** **Document on control of risks (in preparation)**

Implementation of new requirements in QMS of NIB, FITO

ISO/IEC 17025: 2017	Main content	Main aspect of change	Solution at NIB, FITO	New / Updated documents
8.6-8.7	improvement, corrective actions	- preventive actions are withdrawn - consideration of **R&O**	**risks included** in the nonconformance handling procedure	**described in 7.10, Quality manual; Document on control of actions, complaints and improvements; Document on control of nonconformances; Form for nonconformances**
8.8	internal audit	**- no need to conduct internal audits every year**, but at planned intervals - **no need that internal audit program shell address all elements of QMS** in one audit - in the audit program the relevance of the activities to be audited, changes and the results of previous audits have to be taken into account	audit plan prepared for 3 years period,	**Internal audit plan;** **Document on internal audits**
8.9	management reviews	- changed inputs to management review - consideration of risks	updated text on management review	**Quality manual;**

Conclusions

The number of new / updated documents and accredited methods

No. of accredited tests - GMOs	**80**
No. of accredited tests - plant pests: **Phytoplasmas** **Bacteria**	 **7** **3**
New documents	**3**
Updated documents	**11**

Conclusions

- **When a lab is accredited for years the majority of risks and opportunities were minimized during implementation and continuous improvement of the QMS**
- **The main purpose of QMS at NIB is to obtain reliable, accurate, traceable, etc. results without many changes and minimal additional administrative work not to increase high expenses for administrative part of diagnosis**
- **There is no requirement for formal methods for risk management or a documented risk management process. Lab can decide to develop or not a more extensive risk management methodology**
- **The implementation of new requirements should be gradually (step-by step, especially in completely new clauses of standard like risks)**
- **The FITO approach of implementation of new requirements is not yet approved by National Accreditation Body – the assessment expected in November**

MANY THANKS TO

EPPO FOR ALL WORK DONE DURING LAST 15 YEARS IN QMS!!!!!

- My colleagues at NIB:

- Marjana Camloh
- Nataša Mehle,
- Tanja Dreo
- Manca Pirc
- Jana Žel


THANK YOU FOR YOUR ATTENTION !