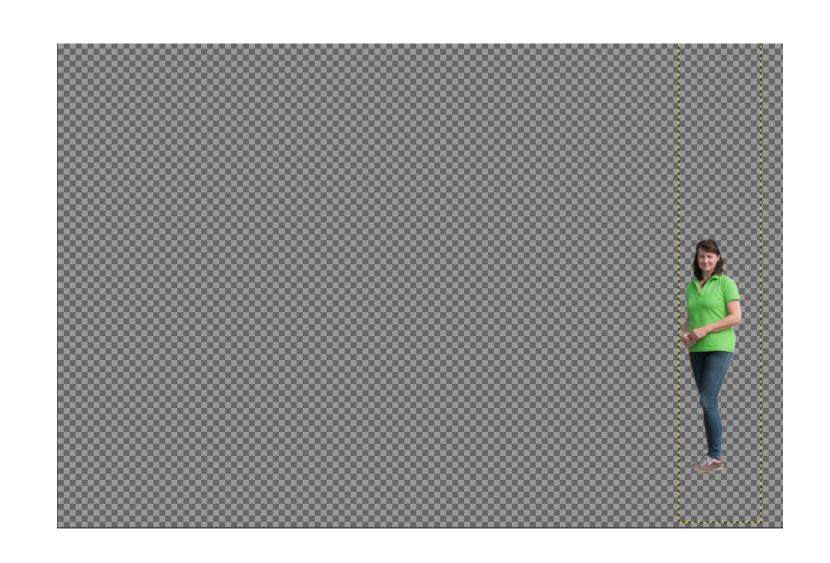


HOW TO MAKE THE LAB QUALITY MANAGER HAPPY

5th EPPO Workshop for Heads of Plant Pest Diagnostic Laboratories Oeiras (PT), 2023-04-19/20

THIS IS OUR LAB QUALITY MANAGER



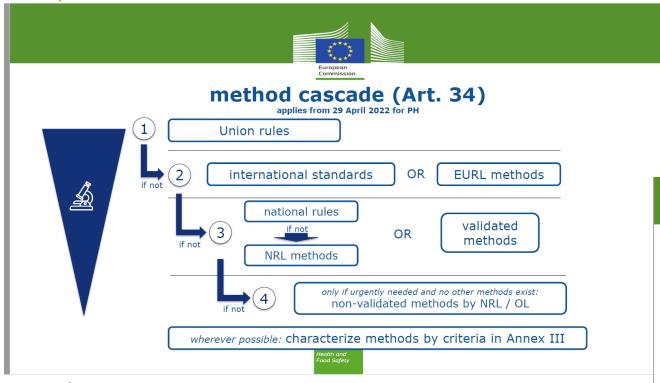
DIVISION OF PLANT PEST DIAGNOSTICS

- -Division of plant pest diagnostics, NRL, Central Institute for Supervising and Testing in Agriculture, Czech Republic
- -Accreditation in accordance with EN ISO/IEC 17025:2018 since 2008
- -Flexible scope of accreditation since 2015
- -Division of Plant Pest Diagnostics has 32 employees in four laboratories (Prague, Havlickuv Brod, Olomou and Opava)
- -NRL for plant pest diagnostics of the Czech Republic designated by Ministry of Agriculture, CZ
- -Responsible for testing of official samples and samples from other official activities
- -Official laboratory for testing of *Tilletia* spp. and storage pests (insect and mites) designated by the Czech Agriculture and Food Inspection Authority

Other main activities:

- EPPO (protocols)
- Designation of official laboratories
- Implementation, validation and harmonization of diagnostics method for testing of official samples and samples on QP and RNQP from other official activities and approaches in the plant health area in the Czech Republic

HOW TO MAKE THE LAB QUALITY MANAGER HAPPY - FRAMEWORK



- EN ISO/IEC 17025:2018 Testing and calibration laboratories
- EN ISO/IEC 17043:2010 Conformity assessment General requirements for proficiency testing
- EPPO PM 7/122 Guidelines for the organization of interlaboratory comparisons by plant pest diagnostic laboratories
- EPPO PM 7/98 Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity
- Etc.

- REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
- COMMISSION DELEGATED REGULATION (EU) 2021/1353

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to the cases and conditions under which competent authorities may designate official laboratories which do not fulfil the conditions in relation to all the methods they use for official controls or other official activities

 COMMISSION NOTICE on the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation)



EURLs, EURCs, NRLs, Art. 92-101



NRLs and EURLs:

- EN ISO/IEC 17025 accreditation for all methods
- · Flexibilities:
 - 1. Groups of methods
 - 2. Flexible scope



HOW TO MAKE THE LAB QUALITY MANAGER HAPPY — REASONS FOR OUR OWN ORGANIZATION OF ILCT

- ensuring the quality of work (credible, informative, effective)
 - Internal/external control of the work quality of laboratory staff, laboratory quality system and verification of relevant parameters of diagnostics methods.
- requirements of the standard/regulation/EK
- designation of official laboratories and their regular control (internal audits connected with their participation in PT).
 - from 2014/five designated official laboratories on the field of plant health
- harmonization of diagnostics approaches of plant pests
- operative, specific (matrix/organism/parameter/date/frequency etc.)
- price
- training purposes
- historically, PT/ILCT aimed on plant health diagnostics were not easily available before EURL PT and still some methods/organisms/matrix and their combinations are not covered well. Many thanks ANSES, EUPHRESCO and Vallitest for their activities in organization of PT and TPS.

HOW TO MAKE THE LAB QUALITY MANAGER HAPPY — PT/ILCT

Department of Proficiency Testing

Since 1996, UKZUZ has been organizing proficiency testing programs for analytical laboratories MPZ UKZUZ. The goal of programs implementation is to enable the laboratories to perform external quality assessment and to help increase reproducibility of laboratory results.

Proficiency Testing (Central Institute for Supervising and Testing in Agriculture, ÚKZÚZ) (eagri.cz)

Regularly organized PT (in one- or three-years period)/main reason - designation and supervision of official laboratories

- Detection and identification of potato cyst nematodes (G. rostochiensis and G. pallida); (soil and cysts)
- Detection and identification of QBP (Clavibacter sepedonicus and Ralstonia solanacearum); (suspensions)
- Detection of Plum Pox Virus/Prunus necrotic ringspot virus/Apple mosaic virus/Prunus dwarf virus (ELISA/Iyophilized plant material)
- Detection and identification of Candidatus phytoplasma mali (PCR/plant material)
- Detection and identification of phytoplasms from AP group ('Candidatus Phytoplasma mali', 'Candidatus Phytoplasma pyri', 'Candidatus Phytoplasma prunorum'); (PCR/DNA)
- Detection and identification of smut fungi Tilletia spp. (grain)

HOW TO MAKE THE LAB QUALITY MANAGER HAPPY — PT/ILCT

ILCT (bilateral/external/internal):

Cooperation with dr. Sebastjan Radišek, Slovenian Institute for Hop Research and Brewing

- Detection and identification of HSVd and CBCVd in hop (plant material)
- Detection and identification of Verticillium species associated with hop (cultures)

Cooperation with some other laboratory or experts using the same method/device or interested in the same target group of organisms.

- Detection and identification of Synchytrium endobioticum (soil)
- Identification of Erwinia amylovora in plant extracts (extracts)
- GC identification of unknown bacterial strains in pure culture (cultures, bilateral cooperation with the Main Inspectorate of Plant Health and Seed Inspection, PL)
- ldentification of Phytopthora spp./Monilinia spp./Sclerotinia spp. (cultures)
- Detection of Pepino Mosaic Virus (ELISA/plant material)

Detection and identification of a target virus/viroid in a blind sample of symptomatic plant 2022 (many thanks for reciprocal organization of bilateral ILCT on biological testing - Blind Samples for Bioassay (viruses) - National Reference Centre - Plant health, Wageningen, the Netherlands

Identification of plant parasitic nematodes (permanent slide)

CRISTAL BALL

Essential procedural infromation:

- 1) No need for ball calibration
- 2) Avoid using positive and negative controls
- 3) Always wear gloves to avoid contamination
- 4) Only one sample at time
- 5) Result is evaluated immediately after the sample is placed in the rack



YOU NEVER WERE THAT SMART



HOW TO MAKE THE LAB QUALITY MANAGER HAPPY — SPECIFIC PROBLEMS

- -"Real" and complex matrices testing of the whole laboratory process including extraction and all the matrices in the scope of accreditation of the lab.
 - (DNA samples)
 - stability (decrease in infection rate) and homogeneity of the "real" samples (twigs/seeds/leaves etc.)
- negative controls of (negative plant material) suitable for virological tests, bigger problem than in positive controls
- ensuring of the homogeneity of samples
- -Testing of the detection part in entomological methods (wood samples/plant material); the majority of entomological PT covered only identification part
- -PT on viruses/phytoplasmas in vectors (matrix insect/mite/nematode)
- -PT on viruses transmitted by seeds (matrix seed)
- budget/time consuming/administration

HOW TO MAKE THE LAB QUALITY MANAGER HAPPY — RISKS



The more tests, the greater the chance of inconsistent work.

There is no way how to make the laboratory quality manager happy :(

THIS IS OUR LAB TEAM IN OLOMOUC + LAB MANAGER

THANK YOU FOR YOUR ATTENTION.

