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Validation of diagnostic tests to support plant health



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**Abstract:**

This deliverable presents the fact sheet, flyer and poster developed to disseminate the project activities.

Partners involved: all partners

HISTORY OF CHANGES		
Version	Publication date	Change
1.0	25 April 2019	Initial version
2.0	11 February 2020	Following the review of the project, modification of the part marked in yellow

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## 1 Purpose

The aim of this deliverable is to present the factsheet, flyer and poster developed to disseminate information on the project and to be used in meetings.

## 2 Methodology

The factsheet was initially developed by UNITO and revised by EPPO in particular to add a section on achievements. This section is intended to be revised on a regular basis (after each steering committee) or more often if needed, at the request of partners, to communicate on achievements. The factsheet is presented in Annex 1. This document will be updated as needed.

The flyer and poster were developed by EPPO and circulated to the whole consortium for comments which were incorporated to prepare the version presented in this deliverable in Annex 2 and 3 respectively.

## 3 Conclusion

These documents should be used by partners to disseminate activities conducted in the project when attending Conferences Workshops... They will be updated as necessary.



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### Validation of diagnostic tests to support plant health

Global food security is the most significant challenge mankind is facing in the 21st century due to the 'perfect storm' of a growing population (estimated to exceed 9 billion by 2050), climate change, demand for energy, increased pressure on natural resources, slowing of agricultural productivity growth and decline in the land area for agriculture. Additionally, although it is estimated that a 50% increase in food production will be needed by 2050, currently a quarter of the world's crops are lost to pests, causing major economic losses and social impacts globally. Protecting crops against these losses from farm to fork is critical for achieving sustainable and competitive agriculture as well as for the protection of biodiversity and ecosystems. Establishing smart surveillance mechanisms is essential for the fulfilment of this important goal, as these enable effective monitoring and control of introduction and spread of plant pests.

Early diagnosis and a rapid response are crucial to reduce the risk of entry and spread of plant pests and ultimately their impacts. Furthermore, it is recognized that plant pests can be managed most effectively when control measures are implemented at an early stage of infestation. National Plant Protection Organizations (NPPOs) routinely conduct inspections supported by pest diagnosis for export certification, import, pest surveillance and eradication programs. In 2016, the Commission on Phytosanitary Measures of the International Plant Protection convention adopted a recommendation on diagnostics recognizing that 'pest diagnosis is a cross-cutting issue that underpins most International Plant Protection Convention (IPPC) activities. In order to take action against a pest, it must be accurately identified. To enable safe trade, pest diagnosis must further be completed quickly and to a high level of confidence'.

Validation is essential to provide information on the performance of the tests that are used in diagnostics. However, most detection and identification tests are currently only validated on an intra-laboratory basis or through limited test performance studies (TPS), and there is a need to further harmonize practices and enhance collaboration with kit producers.

### What is VALITEST and achievements so far

#### What is VALITEST?

**VALITEST** aims at producing validation data for the detection and identification of plant pests and will include two rounds of Test Performance Studies (TPS).

The first round will include combinations of pest/test/matrix, prioritized based on the expertise of the project's consortium for the following pests: *Erwinia amylovora*, *Pantoea stewartii* subsp. *stewartii*, *Citrus tristeza virus*, *Plum pox virus*, *Fusarium circinatum* and *Bursaphelenchus xylophilus*.

The second round will include other combinations based on the needs expressed by various stakeholders. Priorities for validation will then be better aligned to their needs and to the market.

To maximize the impact of the project, calls of interest will be organized to include in the validation programme, kits from suppliers outside the consortium and allow participation in the TPS of interested, proficient laboratories.

Current harmonized procedures in Plant Health for validation and organization of TPS will be improved by including appropriate statistical approaches and by adapting the process for new promising technologies, such as High Throughput Sequencing (HTS) also called Next Generation Sequencing (NGS).

Liaison with regional and international standardization bodies will allow large dissemination of validation data obtained in this project especially by their inclusion in harmonized diagnostic protocols.

The outcomes of the project will stimulate, optimize and strengthen the interactions between stakeholders in Plant Health for better diagnostics and lay the foundations for structuring the quality and the commercial offers for plant health diagnostics tools thanks to a dedicated association and a quality charter.

## Activities

### Validation of tests for identified needs and specific pests

VALITEST will coordinate (prepare and organize) the tests' validation and running of test performance studies for prioritized pests in a range of matrices and for a range of diagnostic technology related platforms (both laboratory and on site-based). The main objective of this work is to produce validation data for the identified tests where no or limited validation data is currently available.

### Improvement of the validation process

VALITEST will improve validation approaches for diagnostic technologies to maximise their usefulness for users (diagnosticians) and decision-makers (at National, European or Regional levels) and their use in routine diagnostics.

In details, the project aims at:

1. Improving the current EPPO Standards for validation of tests for plant pest diagnostics (PM 7/098) and for the performance of interlaboratory comparisons (PM 7/122) by incorporating new statistical tools and predictive models;
2. Developing best practice guidelines;
3. Improving generic approaches for the validation and developing best practice guidelines for the validation and application of non-targeted (generic) diagnostic procedures, using next generation sequencing procedures (NGS) for viruses detection, in plant pest diagnostics as a model.

### Quality assurance of reference materials for validation purposes

VALITEST will establish and evaluate guidelines for quality assurance and Standard Operating Procedures (SOPs) for the production of the different types of reference materials used in validation studies for phytosanitary tests including possible quantification of targets in reference material.

### Analysis of demand for testing and impacts

This activity relates to a better understanding of the demands for current and future testing options:

1. To support plant health policies by engaging with stakeholders to ascertain views on and demand for existing tests and operating procedures as well the attributes that lead to adoption for future tools.
2. Assess the end markets for tests including their potential market (e.g. reduction in yield losses) and non-market (e.g. reductions in woodland losses) impacts.

This engagement with stakeholders incorporates elements of the multi-actor approach in considering the demand for and benefits from the validation of existing tests but also with the examination of their requirements for future tests. In addition to the validation of the tests, this approach introduces an element of co-design with end-users that can inform the design of tests and procedures and prioritisation of targets that could assist in bringing such products to the market more rapidly.

### Optimization of proficiency evaluation for a horizontal assessment

VALITEST first of all aims at validating diagnostic tests available for a selection of relevant plant pests. The goal of using validated tests is to ensure the quality of the results based on which control decisions will be taken. However, in the case of tests performed in laboratories, the targeted level of performance of a validated test is only ensured if it is performed by a laboratory regularly showing its proficiency through proficiency tests which cannot be organized for all the diagnostic tests on the market.

VALITEST will develop guidelines following a horizontal approach allowing proficiency testing to be undertaken without the laboratories having to participate in proficiency tests for all the tests used. The outcome of this activity will represent an option for end users of validated tests, but also possible new services for SME.

### Dissemination, communication and training

VALITEST will:

1. Disseminate the validation data generated during the project and gather additional validation data available in plant pest diagnostic laboratories and make these data publicly (and freely) available.
2. Disseminate the results of the project to a wide public including researchers, policy makers and other stakeholders, via different meetings organized at EPPO and EU levels, webinars and through a project website.
3. Ensure future harmonization of validation processes across the EU region by building capacities on validation processes.
4. Build capacities of diagnostics laboratories to perform tests validated in the project by targeted training.

### Market exploitation of the project results

One of the project's main aims is to swiftly bring onto the market tests validated according to international standards and produced by the SMEs manufacturing diagnostic kits.

To achieve this goal, the project's work will be made widely known in order to commercially exploit the results from the project, to ensure market sustainability and to enhance competitiveness of the SMEs internationally.

In this activity, the establishment of an EU Association of the Plant Health Diagnostic Industry will ensure the market sustainability of the SMEs by facilitating dialogue with decision makers. The development of an EU Plant Health Diagnostics Charter will permit SMEs to increase their competitiveness and will contribute to the quality and reliability of their product worldwide.

## Some achievements on 2019-08-31

Surveys have been carried out on

- The tests currently performed in plant pest diagnostic laboratories and validation data available for the pests selected for the first round of Test Performance Studies. These are *Erwinia amylovora*, *Pantoea stewartii* subsp. *stewartii*, *Citrus tristeza virus*, *Plum pox virus*, *Fusarium circinatum* and *Bursaphelenchus xylophilus*.
- The needs of users of the EPPO database on Diagnostic Expertise
- Current testing priorities of stakeholders
- Validation data available
- Requirements for new or improved tests
- Use of on-site testing kits
- Use of High Throughput Sequencing technologies in plant pest diagnostic laboratories

The surveys are and will be used

- To identify the pests (and tests) on which the second round of Test Performance Studies should be focused.
- To redesign the EPPO Database on diagnostic expertise.

**First round of Test Performance Studies has been launched**, and samples circulated to participants (see below). The analysis of the results of each TPS is ongoing.

Pest	Tests	Number of participants registered	Number of countries	Number of samples prepared
<i>Erwinia amylovora</i>	6 tests (real-time PCR, LFDs and LAMP)	32	20	920
<i>Pantoea stewartii</i> subsp. <i>stewartii</i>	6 tests (real-time PCR, PCR)	23	16	460
<i>Citrus tristeza virus</i>	11 tests (ELISA, TPIA, Conventional RT-PCR, Real-time RT-PCR, RT-LAMP and ImmunoStrip)	17	11	1656
<i>Bursaphelenchus xylophilus</i>	5 tests (conventional PCR, real-time PCR, LAMP)	21	18	430 DNA extracts 280 spiked wood extracts
<i>Plum pox virus</i>	8 tests selected (RT-PCR, real-time RT-PCR, DAS-ELISA)	17	12	697
<i>Fusarium circinatum</i>	6 tests (plating, PCR, real-time PCR)	20	15	640

The organisation of the second round of TPS has started. The pests have been selected and the organizers identified. These are: *Tomato spotted wilt tospovirus* (NIB), *Xylophilus ampelinus* (FERA), *Xanthomonas citri* pv. *citri* (ANSES), *Tomato brown rugose fruit virus* (CREA), *Cryphonectria parasitica* (UNITO) and *Plum pox virus* (ANSES).

A list of **general minimum criteria for the production of reference materials** (RMs) to be used in interlaboratory studies (including validations through test performance studies (TPS)) was developed as well as a **general standard operating procedure (SOP) for the production of reference material (RM)** for use in plant health diagnostics.

**Statistical methods that could be used to improve the reporting of test performance criteria have been identified** and will be evaluated during the VALITEST project and also by EPPO diagnostic Panels and proposed for possible inclusion in the EPPO PM 7/98 (3).

**AND MUCH MORE IN PROGRESS.....**

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## Keywords

Biochemistry and molecular biology, Quality management, Plant pests, Diagnostic technology, Certification, Verification, Validation, Technical Compliance, Standards, Plant health, Pest, Diagnostic, Detection, Identification, Test Performance Study, Validated protocols, Next Generation Sequencing, Training, Reference material, Proficiency, High Throughput Sequencing.

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## The Consortium

1. French Agency for Food, Environmental and Occupational Health & Safety, ANSES (France) Coordinator
2. University of Turin, Centre of Competence for Innovation in the agro-environmental field (AGROINNOVA), Italy
3. Federal Department of Economic Affairs, Education and Research EAER – Agroscope, Switzerland
4. Bioreba AG, Switzerland
5. Loewe Biochemica GmbH, Germany
6. European And Mediterranean Plant Protection Organization, (International Organization)
7. Fera Science Limited, United Kingdom
8. National Institute of Biology, Slovenia
9. Gembloux Agro-Bio Tech - University of Liège, Belgium
10. Netherlands Food and Consumer Product Safety Authority, Netherlands
11. ClearDetections B.V., Netherlands
12. Stichting Wageningen Research, Netherlands
13. International Plant Analysis and Diagnostics SRL (Ipadlab), Italy
14. Sediag, France
15. Council for Agricultural Research and Economics (CREA), Italy
16. The Main Inspectorate of Plant Health and Seed Inspection (PIORIN), Poland

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**End date:** April 30th 2021

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<https://www.valitest.eu/>

<https://twitter.com/ValitestProject>

<https://www.flickr.com/people/154720643@N08/groups/>

## Research Institutions

**anses**  
 French agency for food, environmental  
 and occupational health & safety  
*Investigate, evaluate, protect*

French agency for food,  
 environmental and  
 occupational health & safety  
<http://www.anses.fr>

**LIÈGE université**  
**Gembloux**  
**Agro-Bio Tech**

Gembloux Agro-Bio Tech -  
 University of Liège  
<http://www.gembloux.ulg.ac.be>

**AGRINNOVA**  
 University of Turin  
<http://www.unito.it>

**NIB**  
 NATIONAL INSTITUTE OF BIOLOGY  
 National Institute of Biology  
<http://www.nib.si/eng>

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 UNIVERSITY & RESEARCH  
 Stichting Wageningen  
 Research  
<http://www.wur.nl/en.htm>

**crea**  
 Consiglio per la ricerca in agricoltura  
 e l'analisi dell'economia agraria  
 Council for Agricultural  
 Research and Economics  
<http://www.crea.gov.it>

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 Federal Department of Economic Affairs,  
 Education and Research EAER  
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 Federal Department of  
 Economic Affairs, Education  
 and Research EAER -  
 Agroscope  
<http://www.agroscope.admin.ch/agroscope/en/home.html>

## Intergovernmental Organization



European and Mediterranean  
 Plant Protection Organization  
<http://www.eppo.int>

## NPPOs

Netherlands Food and Consumer  
 Product Safety Authority  
 Ministry of Agriculture,  
 Nature and Food Quality  
**Netherlands Food and  
 Consumer Product Safety  
 Authority**  
<http://www.nvwa.nl>



**PIORIN**  
 The Main Inspectorate of Plant  
 Health and Seed Inspection  
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## SMEs & Industry

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## ANNEX 2 VALITEST Flyer



(2018-05 to 2021-04)

Validation of diagnostic tests to support plant health

### Introduction

Early diagnosis and a rapid response are crucial to reduce the risk of entry and spread of plant pests and to limit their damage.

National Plant Protection Organizations (NPPOs) routinely conduct inspections supported by pest diagnosis for export certification, import, pest surveillance and eradication programs.

Validation is essential to provide information on the performance of the tests that are used in diagnostics. However, most detection and identification tests currently in use have limited validation data available and there is a need to further harmonize practices.

During the three years of the project VALITEST will:

- Organize surveys to gather validation data on existing tests and assess the needs for testing expressed by the stakeholders
- Organize 2 rounds of Test Performance Studies (TPS) on selected pests to produce validation data. The pests targeted in the 1st round are: *Erwinia amylovora*, *Pantoea stewartii* subsp. *stewartii*, *Citrus tristeza virus*, *Plum pox virus*, *Fusarium circinatum* and *Bursaphelenchus xylophilus*.
- Define quality requirements for biological material to be used for test performance studies
- Organize training workshops on validation and develop webinars and video tutorials on the validation process
- Improve the validation process and optimize proficiency evaluation
- Define an EU Plant Health Diagnostics Charter for Industry

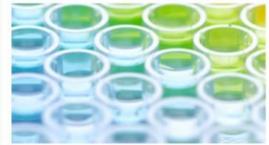
For more information see <https://www.valitest.eu>  
or send a message to [contact@valitest.eu](mailto:contact@valitest.eu)



### Objectives of the project

1. To provide more complete and precise descriptions of the performance of diagnostic tests
2. To stimulate, optimize and strengthen the interactions between stakeholders in Plant Health for better diagnostics
3. To lay the foundations for structuring the quality and the commercial offers for plant health diagnostics tools

VALITEST - a project to improve the validation framework in the EU for plant pest diagnostic



# List of Partners

## Research Institutions

**anses**  
 French agency for food, environmental and occupational health & safety  
*Investigate, evaluate, protect*  
 French agency for food, environmental and occupational health & safety  
<http://www.anses.fr>

**AGRINNOVA**  
 University of Turin  
<http://www.unito.it>

**crea**  
 Consiglio Nazionale delle Ricerche  
 Council for Agricultural Research and Economics  
<http://www.crea.gov.it>

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**YSEDIAG**  
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<http://www.ipadlab.eu/index.php/en>

**BIOREBA**  
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## Intergovernmental Organization

**eppo**  
 European and Mediterranean Plant Protection Organization  
<http://www.eppo.int>

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 Netherlands Food and Consumer Product Safety Authority  
<http://www.mvwa.nl>

**PIORIN**  
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<http://www.piorin.gov.pl>



**VALITEST - a multi-actor project**

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