Periodic Technical Report

Part B

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Definition of terms

Interlaboratory tests or **interlaboratory comparisons** (EPPO, PM 7/122 (1))[1]: include both test performance studies and proficiency tests.

Method (EPPO, PM 7/76 (5))[2]: includes bioassay methods, biochemical methods, fingerprint methods, isolation/extraction methods, molecular methods, morphological and morphometrical methods, pathogenicity assessments, and serological methods.

National Reference Laboratory (NRL): NRLs are officially nominated by the competent authorities of the EU Member States. The tasks of the NRL are listed in Regulation (EC) No 2017/625[3] on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare, and plant health regulations.

Pest (IPPC, ISPM 5)[4]: species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

Proficiency Testing (EPPO, PM 7/76 (5))[2]: Establishing the competence of a laboratory in analysing defined samples using their established test (evaluation of the competence of the laboratory).

Reference material (EPPO, PM 7/76 (5))[2]: Material appropriate to the test and diagnosis being performed such as live cultures, infected plant material, DNA/RNA preparations, images of a diagnostic quality or mounted specimens. The reference material used should be documented and appropriate to the test and diagnosis being performed. It should be ensured that the material used is producing the features for which it was selected for example expressing a desired antigen for use in serological diagnosis, or displaying specific physical features (e.g. sporulation) if used for morphological diagnosis.

Test (EPPO, PM 7/76 (5))[2]: The application of a method to a specific pest and a specific matrix.

Test performance study (TPS): Evaluation of the performance of one or more tests by two or more laboratories using defined samples (evaluation of a test). A TPS is also referred to as ring tests or collaborative trials (EPPO PM 7/76 (5)[2]). Test performance study is part of validation studies and usually follows in-house validation of tests.

Verification (ISO 9000:2015): confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

Validation (ISO 9000:2015): confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

[1] EPPO (2014), PM 7/122 (1) Guidelines for the organization of interlaboratory comparisons by plant pest diagnostic laboratories, Bulletin OEPP/EPPO Bulletin 44 (3), 390–399

[2] EPPO (2018), PM 7/76 (5) Use of EPPO Diagnostic Standards, Bulletin OEPP/EPPO Bulletin 48 (3), 373–377

[3] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products,

[4] IPPC (2019) – ISPM 5. Glossary of phytosanitary terms. Roma, FAO, 38 p

Acronyms

DMP: Data Management Plan
DNA: DeoxyriboNucleic Acid
DoA: Description of Actions
DROP: Digital Repository Object Portal
ELISA: Enzyme-Linked ImmunoSorbent Assay
EPDIA: EU Plant health Diagnostic Industry Association
EPPO: European and Mediterranean Plant Protection Organization
EURL: European Union Reference Laboratory
HTS: High Throughput Sequencing
IPPC: International Plant Protection Convention
LAMP: Loop mediated isothermal AMPlification
LFD: Lateral Flow Device
NGS: Next Generation Sequencing
NPPO: National Plant Protection Organization
MB: Management Board
NEC: Non European Countries
NRL: National Reference Laboratory
PCR: Polymerase Chain Reaction
POPD: Protection Of Personal Data
PT: Proficiency test
RM: Reference Material
RNA: RiboNucleic Acid
SC: Steering Committee
SOP: Standard Operating Procedure
TPS: Test Performance Study

1 Explanation of the work carried out by the beneficiaries and Overview of the progress

INTRODUCTION

VALITEST aims at producing validation data for the detection and identification of plant pests and includes two rounds of Test Performance Studies (TPS).
The first round includes combinations of pest/test/matrix, prioritised based on the expertise of the project consortium partners for the following pests: *Erwinia amylovora*, *Pantoea stewartii* subsp. *stewartii*, Citrus tristeza virus, Plum pox virus, *Fusarium circinatum* and *Bursaphelenchus xylophilus*.
The second round includes six pests selected based on the results of the survey organised in the framework of WP4 (§1.3.4). This prioritisation process has been implemented in such a way that the project's validation actions are in line with the needs of the stakeholders and of the market. The selected pests are: Tomato brown rugose fruit virus, Tomato spotted wilt virus, Plum pox virus *(on site testing), Xanthomonas citri pv. citri, Xylophilus ampelinus* and *Cryphonectria parasitica.*
To maximise the impact of the project, calls of interest have been organised in order to include in the TPS programme, kits from suppliers outside of the consortium and to allow participation in the TPS of interested proficient laboratories.
Current harmonised procedures in Plant Health for validation and organisation of TPS are being 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 standardisation bodies will provide the means for a wide dissemination of the validation data obtained in this project especially by their inclusion in harmonised diagnostic protocols.
The outcomes of the project will stimulate, optimise 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 (WP1)
VALITEST coordinated (prepared and organised) a first round of test performance studies and a second round is under preparation. In both cases, the objective is to produce validation data i) for prioritised pests ii) in a range of matrices iii) for the identified tests where no, or limited, validation data is currently available and iv) for a range of diagnostic platforms (both laboratory and on-site based).

Improvement of the validation process (WP2)
VALITEST improves 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 to:
1. improve the current EPPO Standards for validation of tests for plant pest diagnostics (PM 7/98[5]) and for the performance of interlaboratory comparisons (PM 7/122[1]) by including new statistical tools and predictive models;
2. prepare the future of diagnostic by developing best practice guidelines;
3. improve generic approaches for the validation and develop best practice guidelines for the validation

[5] EPPO, PM 7/98 (3) Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity, Bulletin OEPP/EPPO Bulletin (2018) 48 (3), 387–404

and application of non-targeted (generic) diagnostic procedures, using next generation sequencing procedures (NGS) for the detection of viruses as a model in plant pest diagnostics.

Quality assurance of reference materials for validation purposes (WP3)
VALITEST establishes and evaluates 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 (WP4)
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.

Optimisation of proficiency evaluation for a horizontal assessment (WP5)
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 reliability 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 proficient laboratory. Proficiency is currently assessed through proficiency tests, which cannot be organised for all the diagnostic tests available on the market. After a first step evaluating of the needs of laboratories, 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 help the laboratories to manage and better show the extent of their competence and their proficiency in testing. This horizontal approach may stimulate the offer of new services by SMEs (such as appropriate proficiency tests)..

Dissemination, communication and training (WP6)
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 organised at EPPO and EU levels, webinars and through a project website.
3. ensure future harmonisation 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 through targeted training.

Market exploitation of the project results (WP7)
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 partners are working to make the project's outputs as widely known as possible 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 ensures the market sustainability of the SMEs by facilitating dialogue with decision-makers. The development of an

EU Plant Health Diagnostics Charter will enable SMEs to increase their competitiveness and will contribute to the quality and reliability of their products worldwide.

OVERVIEW OF THE PROGRESS

VALITEST organised surveys to gather validation data on existing tests and assess the needs for testing expressed by the stakeholders

In details, surveys have been carried out on:

- The tests currently performed in plant pest diagnostic laboratories for the pests selected for the first round of Test Performance Studies (*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
- The current testing priorities of stakeholders
- Validation data available
- Requirements for new or improved tests
- The use of on-site testing kits
- The use of High Throughput Sequencing technologies in plant pest diagnostic laboratories
- The needs of the laboratories for proficiency testing and the applicability of a horizontal approach

The surveys are and will be used:

- To identify the pests (and tests) for the second round of Test Performance Studies
- To assess the demand for and benefits from validation
- To redesign the EPPO Database on diagnostic expertise
- To propose guidance and initiate discussion with accreditation bodies concerning the horizontal proficiency testing approach

The first round of Test Performance Studies is finalised, and samples have been circulated to participants (Table 1). The analysis of the results of each TPS is ongoing.

Table 1. Description of TPS Round 1

Pest	Number of tests included	Number of participants	Number of countries	Number of samples prepared
Erwinia amylovora	6	32	20	920
Pantoea stewartii subsp. *stewartii*	6	23	16	460
Citrus tristeza virus	11	17	11	1656
Bursaphelenchus xylophilus	5	21	18	430 DNA extracts 280 spiked wood extracts
Plum pox virus	8	17	12	697
Fusarium circinatum	6	20	15	640

The organisation of the second round of TPS has started. The pests have been selected and the organisers identified. These are (TPS organisers in brackets): 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)) has been 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 can 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.

As planned, the project management, in association with some work packages, provided appropriate work and valorisation frameworks by drafting a data management plan, a dissemination and training plan, a plan for the exploitation of results and a plan for the protection of personal data.

1.1 Summary of Deliverables and Milestones

The deliverables and milestones due for the first reporting period M1-M18 are indicated in bold type in the text.

1.1.1 Deliverables

WP No	Deliverable No	Deliverable name	Delivery date (Annex 1)	Actual Delivery date	Comments (for deliverables delayed by more than 2 months)
WP1	D1.1	Report detailing the minimum performance parameters to select tests for validation and selection of laboratories for TPS	31 Jul 2018 (Month 3)	4 March 2019 (Month 11)	A first version of D1.1 was prepared and submitted to TPS organisers month M5. Further to discussions in WP1, D1.1 had to be reviewed to add an explanation for the evaluation of each criteria (quantitative/qualitative description), a weight to each criteria and the methodology used. The deliverable was postponed to month M11.
WP1	D1.2	List of tests for validation - Round 1	30 Sep 2018 (Month 5)	4 March 2019 (Month 11)	A first version of D1.2 was prepared and submitted to TPS organisers month M6. This version only included the methods and not the final list of tests to be validated for each TPS, as described in the DoA. It was decided to postpone the D1.2 deadline until February 2019 (M10) to give time to TPS organisers to select final tests for TPS. Indeed, it is important to have clear common rules for the selection of the tests for validation as these rules apply also for Round 2 of the TPS.
WP3	D3.1	List of the criteria the reference materials have to meet for use in validation studies	31 Dec 2018 (Month 8)	1 March 2019 (Month 11)	
WP3	D3.2	Development draft Standard Operating Procedures (SOPs) available for the production of the reference materials identified in Task 3.1	28 Feb 2019 (Month 10)	4 March 2019 (Month 11)	
WP3	D3.3	Guidelines and Standard Operating Procedures (SOP) finalised for the production of the reference materials	31 Oct 2019 (Month 18)	19 Nov 2019 (Month 19)	
WP4	D4.1	Report on stakeholder priorities for tests and general prioritization framework	31 Oct 2019 (Month 18)	12 Dec 2019 (Month 20)	

WP5	D5.1	Analysis of the needs of the laboratories and applicability of the horizontal proficiency testing approach based on the questionnaire answers	31 Oct 2019 (Month 18)	15 Nov 2019 (Month 19)	
WP6	D6.1	Project website and social media accounts	31 Jul 2018 (Month 3)	14 Sept 2018 (Month 5)	
WP6	D6.2	Survey on the needs of users of the EPPO Database and exploitation of the data	31 Aug 2018 (Month 4)	28 Feb 2019 (Month 10)	It was not possible to have the survey ready month M4 because of the summer period. It was prepared month M6 and the survey was sent month M7. Therefore, data exploitation could be done month M10
WP6	D6.3	Inventory of validation data available	31 Aug 2018 (Month 4)	30 Oct 2018 (Month 6)	
WP6	D6.4	Dissemination and Training plan	31 Oct 2018 (Month 6)	30 Oct 2018 (Month 6)	
WP6	D6.5	Information materials (project fact-sheet, flyers, poster)	30 Apr 2019 (Month 12)	25 April 2019 (Month 12)	
WP6	D6.6	Report on improved version of the validation section of the EPPO Database on diagnostic expertise, including new data provided by laboratories	31 Jul 2019 (Month 15)	12 Dec 2019 (Month 20)	Deliverable 6.6 is dependent on deliverable 6.2, which was delayed (month 10 instead of Month 4 due to the delayed start of the project and the summer period that prevented us to do a proper survey), so this deliverable was equally delayed i.e. delivered by month 20 instead of Month 15. However, in deliverable 6.2 some proposals have already been made for the improvement of the section “validation” of the database.
WP7	D7.1	Results exploitation plan	30 Apr 2019 (Month 12)	13 Dec 2019 (Month 20)	Due to some difficulties including delays in other tasks, difficulties in receiving feedback and because of a problem of resources management in the company (absence of a project manager), the deliverable has been postponed to month M20.
WP8	D8.1	Data Management Plan	31 Oct 2018 (Month 6)	30 Oct. 2018 (Month 6)	
WP8	D8.2	Periodic report	31 Oct 2019 (Month 18)	26 Dec 2019 (Month 20)	
WP8	D8.3	Data Management Plan first revision	31 Oct 2019 (Month 18)	27 Nov. 2019 (Month 19)	
WP9	D9.1	POPD - Requirement No. 1	31 Oct 2018 (Month 6)	21 Dec 2018 (Month 8)	

WP9	D9.2	NEC - Requirement No. 2	31 Jul 2018 (Month 3)	25 Feb 2019 (Month 10)	D9.2 includes personal data flows to and from Europe. Deliverable 9.1 (POPD) and 8.1 (Data Management Plan) had to be finalised before deliverable 9.2 was written. Furthermore, a new staff member arrived in the coordination team in November 2018 (month M7) and helped with the preparation of this deliverable.

1.1.2 Milestones

WP No	Milestone No	Milestone name	Delivery date (Annex 1)	Actual Delivery date
WP1	M1.1	Setting of minimum performance parameters, criteria and list of tests - Round 1	31 Dec 2018 (Month 8)	21 Jan 2019 (Month 9)
WP1	M1.2	TPS plans - Round 1	31 Dec 2018 (Month 8)	18 Feb 2019 (Month 10)
WP1	M1.3	Dispatch of samples panel for all TPS - Round 1	31 March 2019 (Month 11)	02 May 2019 (Month 13)
WP2	M2.1	First draft of recommendations for the revision of the EPPO Standards PM 7/98 and PM 7/122 for validation studies (including TPS)	30 June 2019 (Month 14)	28 June 2019 (Month 14)
WP3	M3.1	Criteria for reference material described	31 Dec 2018 (Month 8)	26 Feb 2019 (Month 10)
WP3	M3.2	Existing guidelines and/of SOP's for actual production of reference material collected	31 Dec 2018 (Month 8)	26 Feb 2019 (Month 10)
WP3	M3.3	Report with SOP's for production of reference material available for WP1 activities	28 Feb 2019 (Month 10)	4 March 2019 (Month 11)
WP3	M3.4	Report on the evaluation by WP1 (TPS organisers) of guidelines and the Standard Operating Procedures (SOPs) available	31 Aug 2019 (Month 16)	23 Oct 2019 (Month 18)
WP4	M4.1	Template for stakeholder survey	31 Jan 2019 (Month 9)	18 Feb 2019 (Month 10)
WP4	M4.2	Identification of criteria for prioritisation of pests/tests for years 2 and 3	31 Jan 2019 (Month 9)	1 March 2019 (Month 11)
WP4	M4.3	Completion of survey and application of prioritisation criteria	30 Apr 2019 (Month 12)	16 April 2019 (Month 12)
WP4	M4.4	Proposition of combinations pests/tests/matrices for the 2nd round of TPS	31 Jul 2019 (Month 15)	04 Sept 2019 (Month 17)
WP4	M4.5	Description of impact case studies and data needs available	31 Oct 2019 (Month 18)	17 Dec 2019 (Month 20)
WP5	M5.1	Questionnaire sent to the laboratories of the EPPO Database on diagnostic expertise	30 June 2019 (Month 14)	22 July 2019 (Month 15)
WP6	M6.1	Draft dissemination and Training Plan presented	31 May 2018 (Month 1)	31 May 2018 (Month 1)

WP6	M6.2	Survey on needs of users of the EPPO Database on diagnostic expertise (section validation data) posted online	31 Aug 2018 (Month 4)	1 Oct 2018 (Month 6)
WP6	M6.3	Analysis of the need for improvement of the validation section of the EPPO Database on diagnostic expertise	30 Apr 2019 (Month 12)	28 Feb 2019 (Month 10)
WP6	M6.4	Minutes of the meetings with policy makers and researchers	31 Jul 2019 (Month 15)	29 Oct 2019 (Month 18)
WP7	M7.1	Draft dissemination and Training Plan	28 Feb 2019 (Month 10)	13 Dec 2019 (Month 20)
WP8	M8.1	Kick-off meeting - SC1	31 May 2018 (Month 1)	31 May 2018 (Month 1)
WP8	M8.2	SC meeting n°1 - SC2	31 Aug 2018 (Month 4)	7 Sept 2018 (Month 5)
WP8	M8.3	SC meeting n°2 - SC3	31 Dec 2018 (Month 8)	14 Dec 2018 (Month 8)
WP8	M8.4	SC meeting n°3 - SC4	30 Apr 2019 (Month 12)	05 Apr2019 (Month 12)
WP8	M8.5	SC meeting n°4 - SC5	31 Aug 2019 (Month 16)	04 Sept 2019 (Month 17)
WP8	M8.6	Mid-term general assembly	31 Oct 2019 (Month 18)	01 Oct 2019 (Month 18)

1.2 Objectives

General objectives

VALITEST's main objective is to improve the reliability of diagnostics in plant health by several different and inter-related approaches:

1. To provide more complete and precise descriptions of the performance of diagnostic tests

Validation data is not available for all tests that are currently widely used in plant pest diagnostic laboratories. This is in particular often the case for high throughput tests such as ELISA. In order to guarantee the quality and validity of the results provided by private laboratories or national authorities involved in official controls, and to comply with the applicable regulations, VALITEST provides **additional validation data and harmonisation** of the testing and validation processes. **An improved framework for validation will allow the production of data for faster decision-making and to support risk management**. This will enhance early eradication of pests, **thereby supporting the improvement of plant health, thus contributing to the sustainability and competitiveness of the European agri-food sectors**.
Furthermore, the improvement of the diagnostic procedures includes the development of tools to maximise the demonstration of the proper use and the respect of the performance of the validated tests. Progressing further with this endeavour, the VALITEST project will enhance harmonisation of controls and surveys in EU countries and beyond.

2. To stimulate, optimise and strengthen the interactions between stakeholders in Plant Health for better diagnostics

Since 1998, the European and Mediterranean Plant Protection Organization (EPPO), an intergovernmental organization responsible for international cooperation in plant protection, has been establishing a work programme in the area of diagnostics to harmonise procedures across the EPPO region. This involves the preparation of pest-specific diagnostic protocols, as well as horizontal standards providing guidance on validation of tests or on performing inter-laboratory comparisons. However, performing validation still mainly relies on initiatives from individual laboratories, although recently several inter-laboratories comparisons have been performed in the framework of Euphresco projects, which are highly valuable for setting standards for analysis at European and international levels (EPPO and IPPC protocols for diagnostics). But despite the active role of EPPO at the regional scale, multiple channels and networks for collecting information about diagnostic tests and needs for development and validation still exist and the mapping of such needs at EU level is also incomplete and not up to date. VALITEST fills this gap **by collecting information from stakeholders** (which include researchers, diagnosticians, policy-makers, inspectors, advisory services, industries, seed companies, growers associations, etc.) **to build a comprehensive description of their needs.**

3. To lay the foundations for structuring the quality and the commercial offers for plant health diagnostic tools

Among the stakeholders in plant health diagnostics, the diagnostic industry is not currently structured in such a way as to be visible as a whole that can be solicited by other stakeholders.
To better answer the needs of end-users, but also to enhance the competitiveness of the plant health diagnostic industry, the companies need to be identified through an appropriate initiative and not only at an individual level. This project provides the **opportunity to establish the foundations for a structure to improve communication concerning offers and demands for plant health diagnostic tests in a sustainable manner.**

The ambition of the project is to go beyond the "mere" production of validation data for diagnostic tests for selected pests by developing guidance and documents for an improved approach to the validation process, and to **serve forthcoming needs of different stakeholders at national and EU levels,**

public or private bodies. This will provide a basis for NRL or EURL activities in Plant Health, improved detection standards for all practitioners, data serving the needs for accreditation and certification of laboratories and for mutual recognition. Furthermore, setting up an appropriate structure for the EU plant health diagnostic industry will promote new possibilities for dialogue between the different stakeholders at EU level and beyond.

1.3 Explanation of the work carried per WP

1.3.1 Work Package 1

Two rounds of Test Performance Studies (TPS) were planned. In round 1, combinations of pest/test/matrix were prioritised based on the expertise of the project consortium and six pests were pre-selected before the beginning of the project (Table 2). Details on the prioritisation and the criteria used are available in Table 1.3.c of Annex 1 of the Grant Agreement. For round 2, combinations of pest/test/matrix were selected based on the results of the survey organised in the framework of WP4 and on the list of pests categorised by the EU (WP1 in collaboration with WP4 and WP6, details can be found in deliverable **D4.1. Report on stakeholder priorities for tests and general prioritization framework**), allowing the priorities to be better aligned with the needs of stakeholders and the market. Organisers of Round 2 were selected through an online poll where each VALITEST consortium partner expressed their interest in organising the 6 TPS. The final list of organisers for Round 2 was approved by the VALITEST consortium. Six pests were selected for TPS Round 2 (Table 3). Details on the prioritisation are available in Table 1.3.d of Annex 1 of the Amendment to the Grant Agreement. In both TPS rounds collaborations with Euphresco projects were established to avoid overlap in particular in TPS Round 1 for *Pantoea stewartii* subsp. *stewartii* and TPS Round 2 for Tomato brown rugose fruit virus and *Cryphonectria parasitica*.

Table 2. Pests and TPS organisers selected for TPS Round 1

Pest	**Pest group**	**TPS Organiser**
Erwinia amylovora	Bacteria	NIB
Pantoea stewartii subsp. *stewartii*	Bacteria	NIB
Citrus tristeza virus	Virus	ANSES
Plum pox virus	Virus	NVWA
Fusarium circinatum	Fungi	FERA
Bursaphelenchus xylophilus	Nematode	ANSES

Table 3. Pests and TPS organisers selected for TPS Round 2

Pest	**Pest group**	**TPS Organiser**
Tomato brown rugose fruit virus	Virus	CREA
Tomato spotted wilt virus	Virus	NIB
Plum pox virus (on site testings)	Virus	ANSES
Xanthomonas citri pv. *citri*	Bacteria	ANSES
Xylophilus ampelinus	Bacteria	FERA
Cryphonectria parasitica	Fungi	UNITO

In general, TPS (Round 1 and Round 2) covered all WP1 tasks mentioned below and carried out as follows:

- Selection of pests (only in TPS Round 2, in collaboration with WP4 and WP6)
- Identification of the TPS organisers (only in Round 2)
- Definition of a list of diagnostic methods for laboratory and on-site detection, definition of the TPS scope and selection of methods
- Collection of available validation data from different sources
- Definition of weighted criteria for the selection of tests according to the TPS scope
- Definition of a list of pre-selected tests for validation (according to the TPS scope), subjected to preliminary testing by the TPS organisers
- Assessment of the results of preliminary in-house testing against the weighted criteria
- Selection of tests for TPS
- Sending invitations to the TPS participants
- Analysis of the eligibility of laboratories interested in participating in the TPS
- Informing the interested laboratories on the results of the above analysis and whether they were selected to take part in the TPS
- Sending contracts to participants and preparation of protocols and other TPS documents
- Preparation and dispatch of samples and reagents
- Performing stability and homogeneity studies of samples for TPS
- Communication with TPS participants to clarify uncertainties when performing TPS
- Collecting TPS results and analysing the data
- Preparation of reports, and dissemination activities

For the needs of the TPS organisation, the following TPS documents were drafted by WP1 leaders and used by the TPS organisers:

- TPS invitation letter
- TPS participant information form
- TPS participant contract (**Appendix 1**)
- TPS technical sheet (general overview of the TPS with information about tests, sample panels, important dates, and detailed experimental protocols for performing each test)
- TPS instruction sheet (to help the TPS participants after receiving the parcel with identification of samples, their storage, analysis, special precautions and submission of results)
- Acknowledgement of samples receipt
- TPS results form
- TPS report as word and presentation templates

1.3.1.1 Task 1.1. Preparation of criteria to select tests for validation and to select laboratories for TPS. (M1-M3). Leader: NIB, NVWA Partners: ANSES, FERA, NIB, NVWA

WP1 partners, who organised the first round of test performance studies (Table 2), discussed performance criteria listed in EPPO protocol PM 7/98 (3)[5] and additional criteria derived from the WP1 partners' expertise. Following the discussion, criteria for selection of tests for TPS for each of the six pests were defined and each criterion was assigned a target value and relative weight, which in some cases differed between laboratory and on-site tests. Similarly, weighted criteria for selection of TPS participants were defined. Additionally, common rules for selection of tests for validation and common rules for selection of TPS participants were defined and described to ensure a transparent selection process. The defined criteria and common rules are described in more details in **deliverable D1.1**. **Report detailing the minimum performance parameters to select tests for validation and selection of laboratories for TPS.**

1.3.1.2 Task 1.2. TPS preparation/organisation. (M4-M22). Leader: NVWA, ANSES and NIB Participants: Round 1: ANSES, FERA, NIB, NVWA. Round 2: ANSES, UNITO, FERA, NIB, CREA.

TPS Round 1

WP1 partners prepared materials and documents for the first round of TPS. Firstly, the scope of testing for each specific pest was defined (available in **deliverable D1.1**) to be able to set the strategy for test selection. Isolates/strains/populations and plant material were collected, as well as available validation data, which were gathered through extensive literature searches, internet searches, from the EPPO database, experience of TPS organisers and the EPPO survey on diagnostic tests used in different laboratories and validation data (in collaboration with WP6). Furthermore, first ANSES and then each Round 1 TPS organiser separately established contacts with different companies and enquired about available products for the detection of the six selected pests. After careful selection of tests for in-house validation, preliminary testing was performed by each Round 1 TPS organiser to collect more validation data about the tests that were selected as candidates to be included in the TPS.

Tables with criteria prepared in **deliverable D1.1** (Task 1.1) were completed for each test with values obtained from literature and in-house validation. Based on these tables, TPS organisers were able to decide whether to select a test for TPS or not. Lists of selected tests for in-house validation and further selected tests for TPS are available and explained in more details in **deliverable D1.2**. **List of tests for validation - Round 1**. The final number of selected tests for use in the TPS for each pest differed from the number of tests planned in Annex 1 of the Grant Agreement (Table 4).

Table 4. Number of planned, validated in-house and finally selected tests for TPS **round 1**

Pest	Planned tests	Tests included in preliminary studies	Tests selected for TPS (methods)
Erwinia amylovora	2-3	9	6 (real-time PCR, LFDs and LAMP)
Pantoea stewartii subsp. *stewartii*	3-5	8	6 (real-time PCR, PCR)
Citrus tristeza virus	5-7	16	11 (ELISA, TPIA, Conventional RT-PCR, Real-time RT-PCR, RT-LAMP and ImmunoStrip) from which 9 performed by each participant (3 out of 5 ELISA tests performed, different for each participant)
Plum pox virus	4-8	22	8 (RT-PCR, real-time RT-PCR, DAS-ELISA) from which 6 performed by each participant (1 out of 3 ELISA tests performed, different for each participant)
Fusarium circinatum	3	7	6 (plating, PCR, real-time PCR)
Bursaphelenchus xylophilus	2-5	6	5 (conventional PCR, real-time PCR, LAMP)

In the meantime, the organisers of the first round of test performance studies also identified potential participants for the first round of TPS and invited them using the contacts from previous studies and contacts collected through the EPPO survey conducted in collaboration with WP6 (mentioned above). To assess the eligibility of interested laboratories to take part in the TPS, invitation letters were sent together with an information form in which potential participants were asked about their expertise with the diagnostic methods, pest groups, quality assurance and available equipment. After receiving answers from interested laboratories, criteria prepared in **deliverable D1.1** (Task 1.1) were used by the TPS Round 1 organisers to select TPS participants and their participation was confirmed by sending them the acceptance e-mail and later also the contract, technical and instruction sheets.

TPS Round 1 organisation was carefully planned for each selected pest/test/matrix combination and specified in Gantt charts. TPS material was prepared and also tested by the TPS Round 1 organisers through performing homogeneity and stability studies. In some cases, the TPS organisers had to extend the stability studies because some of the TPS participants did not manage to perform the analyses before the deadline specified in the technical sheet. TPS samples were dispatched together with an instruction sheet, acknowledgement of receipt of the panel of samples and a results form for the participants to fill in after performing tests. WP1 partners (as well as other VALITEST partners) also took part in TPS Round 1 as participants and performed the tests selected for the TPS for which they registered. TPS participants sent back the completed results forms to the organisers, who analysed the TPS results. During the analysis of the results, TPS organisers had to exclude the results from some TPS participants because of the suspicion of contaminated samples or suspicion that analyses were not performed according to the provided protocols.

TPS Round 2

Selected WP1 partners organised the second round of test performance studies (Table 3). They defined the scope of testing for each of the six pests selected to be included in TPS Round 2 and set the strategy for method/test selection, which will be included in deliverable D1.3. List of tests for validation - Round 2**.** In collaboration with WP2, a recommended number of samples for each TPS was defined to meet the

requirements for an appropriate statistical analysis. Another collaboration was established with WP3 in which WP1 partners assisted in the evaluation of the list of criteria (**deliverable D3.1. List of the criteria the reference materials have to meet for use in validation studies**) and standard operating procedure (SOP; **deliverable D3.2. Development of draft SOPs available** and **deliverable D3.3. Guidelines and SOP finalised**) for the production of reference materials, which deliverables were prepared by WP3.

Furthermore, criteria for selection of tests and participants, defined during the preparation phase for the first round of TPS were modified according to lessons learnt from this first round. Some criteria needed to be added, to better justify the selection of a test, e.g. the criterion about the appropriately selected target of the test. Also, some criteria were made more specific, or removed, as they were not important for the selection of tests or the information was not always possible to obtain. In addition, other documents from TPS Round 1 (Invitation letter with Information form) were modified to better fit the modified criteria for selection of participants and to include or emphasise important information for participants, which was not clear enough in the earlier version of documents. The TPS Round 2 organisers used contacts from TPS Round 1 and other previous studies to invite potential participants for Round 2.

Again, as in TPS Round 1, isolates/strains and plant material were collected, as well as validation data, which was gathered through extensive literature searches, internet searches, from EPPO database and experience of TPS organisers. As for TPS Round 1, first ANSES and then each TPS Round 2 organiser separately established contact with different companies and inquired about available products for the detection of the six selected pests. Furthermore, organisers of TPS Round 2 discussed with commercial kit providers regarding the possible modifications of kit components/protocols to be able to compare as many tests as possible and include them in the second round of test performance studies.

At the moment, as in TPS Round 1, weights for the criteria for each of the six pests are being defined and each criterion will be assigned also a target value. Weights and target values are in some cases expected to differ between laboratory and on-site tests. At the same time, preliminary in-house validations are being performed to help with the selection of tests for TPS Round 2.

1.3.1.3 Task 1.3. Completion of the test performance studies. (M11-M26). Leader: NVWA, ANSES and NIB Participants: all partners except EPPO

WP1 partners have collected the TPS results and started the analysis. The results are first to be discussed with companies from the VALITEST consortium to be able to appropriately anonymise the commercial names of kits, if needed. Currently, the TPS reports for TPS participants are being prepared, while the final TPS Round 1 report will be finalised in April 2020.

Furthermore, a document, prepared in collaboration with WP7, describes and explains the selection of tests for TPS Round 1 and gives recommendations for further test selection process, which will be included in the Annex to deliverable D1.4: “Explanation for test selection”.

The analysis of the extent of each TPS included: the number of tests selected, the number of (potential) participants from EU/non-EU countries and consortium/non-consortium across different stages of TPS: planned in the budget preparation (partners), interested participants (EPPO survey), invited potential participants, potential participants who responded to the invitation letter, selected laboratories (based on criteria), rejected laboratories (based on criteria), registered laboratories, participants who performed analysis and participants whose results were taken into consideration for TPS results analysis
Key descriptors of the TPS are provided in Figures 1 to 4. Most TPS participants were from EU countries and some from non-EU countries. Distribution of participants between consortium partners and participants outside the consortium was balanced: some TPS slightly favouring consortium partners while other TPS included more participants from outside of consortium. The TPS allowed to collect a large number of valid data sets.

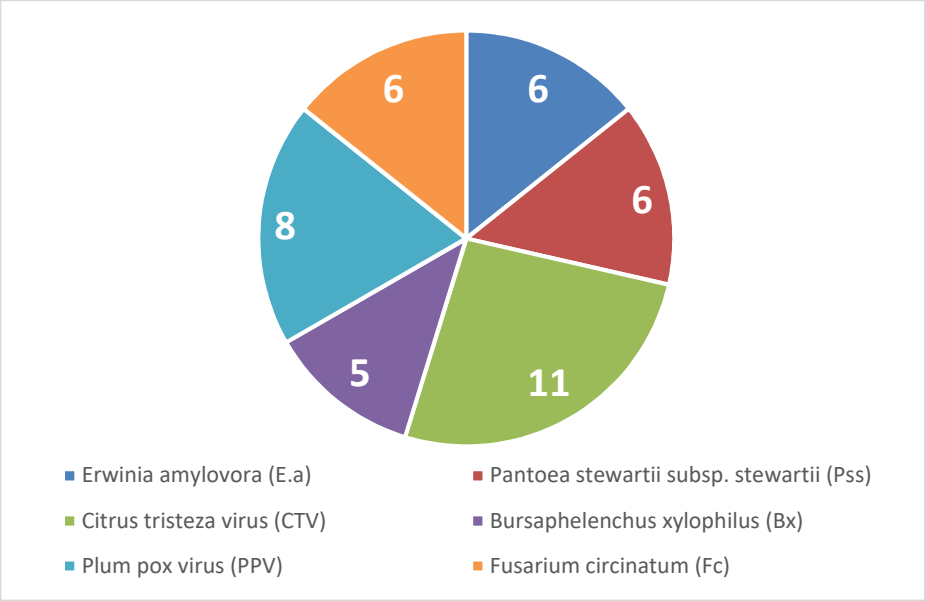

Figure 1. TPS round 1 - Number of tests evaluated per pest

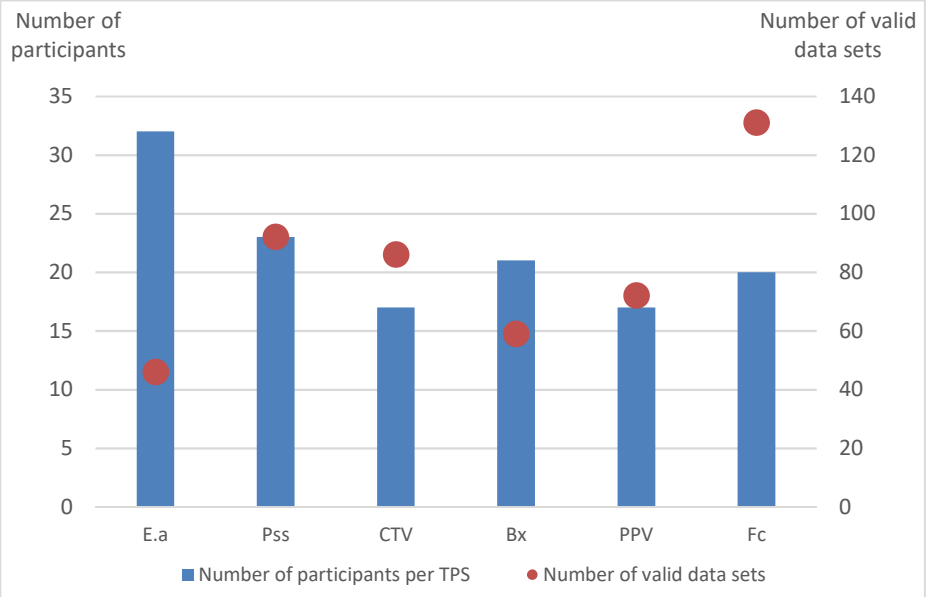

Figure 2. TPS round 1 – Total number of participants and number of valid data sets per TPS

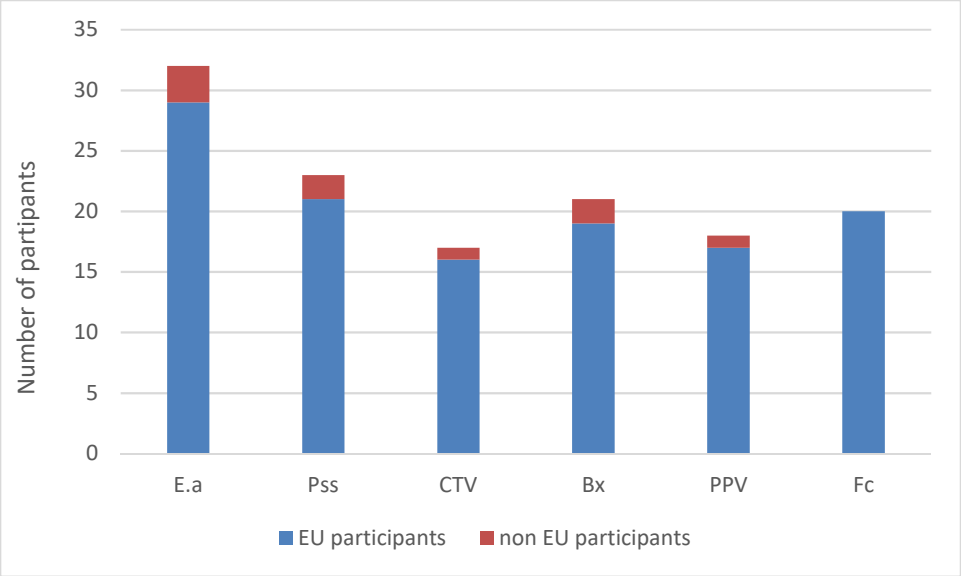

Figure 3. TPS round 1 - Type of participants per TPS: EU / non EU

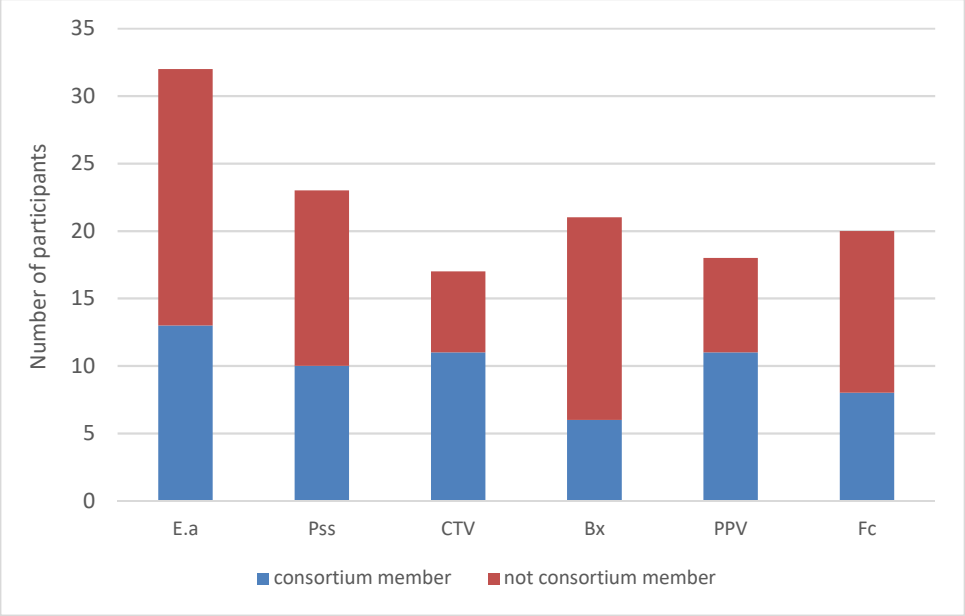

Figure 4. TPS round 1 - Type of participants per TPS: consortium member / not consortium member

1.3.1.4 Task 1.4. Exploitation of the results. (M15-M36). Leader: ANSES and NIB Participants: Round 1: ANSES, FERA, NIB, NVWA. Round 2: ANSES, UNITO, FERA, NIB, CREA.

Publications and presentations of TPS results will be carried out at the end of the analysis of results (Spring 2020).

1.3.1.5 Other work

WP1 partners were also involved in other activities to improve the TPS organisation in Round 1 and 2 and further interlaboratory comparison tests. Efforts were made to harmonise the presentation of TPS results across different TPS. Harmonisation was achieved by using EPPO terminology from EPPO PM 7/98 (3)[5] and EPPO PM 7/76 (5)[2] and with the decision on how to define outliers. Collaboration with WP6 enables active dissemination of WP1 activities through the VALITEST website and social media (Twitter) throughout the whole duration of the project.

1.3.2 Work package 2

1.3.2.1 Task 2.1. Developing provisional guidelines for a new validation approach. (M1-M36). Leader: ULG and ANSES Participants: UNITO, EPPO, WBF, FERA, NIB, WR, CREA, GIORIN.

The objective of Task 2.1 is to develop provisional guidelines for a new validation approach to be considered in the revision of the EPPO Standards PM 7/98 (3)[5] and PM/122 (1)[1]. It has the following milestones/deliverables:

- **Milestone M2.1 – First draft of recommendations for the revision of the EPPO Standards PM 7/98 and PM/122**
- Deliverable 2.1 – Guidelines for the revision of the EPPO Standards PM 7/98 and PM/122 for validation studies (including TPS).

The work started with a literature review (more than 75 scientific papers) of statistical tools in use within and outside the plant health domain and a summary of the review has been compiled in an internal document. The choice of the statistical methods for data analysis of the performance criteria has been based on the applicability of the method in the context of plant health diagnostic laboratories, the minimum number of samples and replicates required for the statistical method to perform correctly, the ease of application and interpretation of the results. The proposed new validation approach uses, wherever possible and whenever applicable, statistical methods recommended by international standards on pathogens/pests diagnostics with examples of their use for plant pest diagnostic tests.

The guidelines focus on an improved statistical analysis of several key parameters in the frame of the validation of a diagnostic test: the analytical sensitivity, the repeatability and reproducibility which are considered core performance criteria of a diagnostic test. In addition, it is proposed to introduce the likelihood ratio as additional parameter in performance evaluation. Likelihood ratios allow an estimation of the probability of a pest infestation in a sample based on the result of the test. Finally, it is proposed to determine the confidence interval for each statistical estimate. Indeed, confidence interval provides information regarding the uncertainty of the estimated performance criteria which are obtained from a limited number of samples.

The proposed statistical tools will improve the comparison of performance criteria between tests by having reliable conclusions from validation studies and better harmonisation of these conclusions. These tools will also assist in the decision-making on test selection during a validation study or in the interpretation of results obtained from diagnostic tests.

Throughout the development of the recommendations for a new validation approach, from December 2018 to June 2019, five web meetings with statisticians and diagnosticians of the WP2 partners (up to 15 participants) have been held, supplemented with extensive emails exchanges, in order to develop guidelines understood and validated by several stakeholders. In addition, the guidelines have also been reviewed by recognised experts in the field (also outside the VALITEST consortium) belonging to ISHI and from members of the EPPO Diagnostic Panels.

The first draft of recommendations for the revision of the EPPO Standards PM 7/98 (3)[5] and PM 7/122 (1)[1] for validation studies (**milestone M2.1**). The guidelines (more than 30 pages) include the selection process for statistical methods, taking into consideration the benefits, limitations and interpretation of each analytical tool. There is a section per performance criteria describing the background, the proposed statistical approach with calculation and interpretation with examples of their application to plant health diagnostic tests and tables and figures as support material.

In preparation of TPS round 2, WP2 partners (in collaboration with WP1 partners) developed in August 2019 a recommended sample panel with specific requirements (e.g. independency of samples). The recommended samples panel ensures the statistical methods can perform correctly. The composition of the recommended panel is as follows:

1. two negative samples in duplicates and independent from each other (4 tubes),
2. two positive samples in duplicates and independent from each other (4 tubes),
3. a five-point serial dilution of a positive control (independent from the positive samples) as follows: the most concentrated dilution in duplicates and the other four-dilution points in triplicates with the last dilution point almost not detectable (14 tubes).

The deliverable D2.1 will be finalised in October 2020 (month M30). This will provide some time to test the statistical tools on real data sets generated by WP1 (see Task 2.2, below) and refine the recommendations, as required.

1.3.2.2 Task 2.2. Application of the new validation approach. (M26-M36). Leader: ULG Participants: ULG.

The objective of Task 2.2 is to apply the new validation approach developed in Task 2.1. (above) and has the following milestones and deliverables:

- Milestone M2.3 – Application of the new validation approach to 5 sets of validation data,
- Deliverable D2.3 – Scientific publication of the results of the validation of approach applied on 5 existing datasets.

The statistical approach proposed in Task 2.1 (above) will be used for the analysis of the data from the test performance study (TPS) organised by WP1. In this way, the methodology will be tested and if required, any adjustment can be made.

Progress towards milestone M2.3 started in September 2019 with application of the new validation statistical approach on the results of the TPS Round 1 organised on Citrus tristeza virus. The preliminary analysis is very informative on the usefulness and practical application of the methodologies. The results will be discussed with statisticians in the coming weeks. The new validation statistical approach will be further tested on other pathogens included in TPS round 1 and round 2.

The results of the analysis will be published in a scientific paper including all co-authors involved in the review of the validation approach (deliverable D2.3).

1.3.2.3 Task 2.3. Developing guidelines to ensure the reliability of non-targeted techniques. (M12-M30). Leader: ULG, FERA and NIB Participants: ANSES, UNITO, EPPO, WBF, WR, CREA, GIORIN.

The objective of Task 2.3 is to develop guidelines to ensure the reliability of high-throughput sequencing (HTS) as a routine test in plant diagnostic laboratories, which could serve as a basis for a new EPPO Standard. It has the following milestones and deliverables:

- Milestone M2.2 – First draft of guidelines for the validation and routine use of HTS in plant diagnostic laboratories, and
- Deliverable 2.2 – “Best practice” guidelines for validation and routine use of HTS test.

ULG planned and exchanged in July 2019 with VALITEST partners and other stakeholders for the timeline of the development of the first draft of HTS guidelines to meet milestone M2.2. ULG also contacted in July 2019 users of HTS all over the world for their participation in reviewing the guidelines (more than 25

participants from 4 continents) in order to get consensus from renowned experts in the field. Moreover, an Euphresco project may start with different but complementary objectives. EPPO will make the link between Euphresco and VALITEST to ensure the two projects complement each other and support each other whenever necessary.

The following skeleton of the HTS guidelines is a result of the COST DIVAS action (FA 1407) and was the backbone for the guidelines:

1. sample preparation and sequencing (with sub-sections on sample, nucleic acid extraction, nucleic acid preparation and sequencing),
2. bioinformatic analysis (with sub-sections on analysis of raw sequences, identification of controls and targets, and interpretation of bioinformatics data),
3. ensuring the quality of diagnostic results through appropriate quality checks,
4. reporting of results (including biological interpretation and confirmation),
5. validation and verification of HTS for routine analysis (including risk analysis)
6. general requirements (such as traceability, data storage, reference materials, outsourcing).

The backbones of the guidelines are based on three brainstorming sessions organised as side-session of scientific conferences (Bari, November 2017; Brussels, February 2018 and finally Liège, November 2018, in the framework of the VALITEST project). Furthermore, a literature review on the application of HTS and guidelines/recommendations outside of plant health domain was completed in August 2019 and a summary of the review of more than 100 scientific papers has been compiled in an internal document.

The guidelines are being drafted chapter by chapter with the support of a small group of experts from the VALITEST project. A first chapter (i.e. ensuring the quality of results with appropriate internal and external quality checks) went through a first round of consultation in September 2019. The following chapters are being drafted: bioinformatics, interpretation, confirmation and reporting of results.

The first draft of the complete guidelines will be sent to the larger group (about 25 persons) for review in several rounds (depending on the comments) between January and March 2020.

1.3.3 Work package 3

1.3.3.1 Task 3.1. Criteria for reference materials production for validation. (M1-M8). Leader: NIB. Participants: WR, EPPO, WBF, UNITO, ANSES, NVWA, IPADLAB, SEDIAG.

A first draft of the criteria required for the production of reference materials (RM), including their definitions was drawn up based on various available literature sources, e.g. existing ISO standards as well as various EPPO standards such as PM 7/76 (5)[2] Use of EPPO Diagnostic Standards, PM 7/84 (2)[6] Basic requirements for quality management in plant pest diagnostic laboratories, PM 7/98 (3)[5] Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity and PM 7/122 (1)[1] Guidelines for the organization of interlaboratory comparisons by plant pest diagnostic laboratories.

A previous FP7 EU-project (Q-collect; Coordination and Collaboration between reference collections of plant pests and diseases for EU Plant Health. Grant agreement number 612712) focused on reference collections of plant pests and diseases within the EU. It not only defined a number of terms, which are relevant for the current VALITEST project, but also identified criteria related to (collections of) biological reference materials.

All possible descriptors of criteria for RM were listed and ranked as more or less important. Criteria were grouped (if meaningful) and minimum criteria for different types of reference material were selected. Teleconferences were held in December 2018 and January 2019 with the WP3 partners to discuss, prioritise and further refine the drafted list of criteria.

Following these discussions and taking into account previous work and relevant international standards, additional criteria were proposed: 'availability', 'purity' and 'commutability'. Identified criteria were defined as a series of levels from the highest to lowest ranking with the lowest ranking considered to be the minimum.

The draft criteria were tested by the organisers of the TPS in round 1 within the VALITEST project which include bacteria, viruses, nematodes and fungi. The systematic and structured approach of describing RMs was found to be useful in promoting transparent descriptions of the RMs used and comparability of TPS.

Using the feedback from the WP1 partners, a final version of the list of criteria the reference materials have to meet for use in validation studies (**D3.1. List of the criteria the reference materials have to meet for use in validation studies**) was completed and submitted.

1.3.3.2 Task 3.2: Standard Operating Procedures for the production of reference materials. (M1-M10). Leader: WR. Participants: NIB, EPPO, WBF, UNITO, ANSES, NVWA, IPADLAB, SEDIAG.

Initially, already available Standard Operating Procedures (SOPs) were requested from VALITEST partners. Although a limited number of SOPs was received from project partners, unfortunately, none of these dealt with the actual production of reference material. Therefore, based on more general information and personal expertise, a general scheme to combine the earlier defined criteria (**D3.1**) and the different steps to be included in the actual production and quality assurance process was drafted.

This initial scheme was based on the different types of reference material that were previously identified and on a flow-chart connecting all the necessary steps, including identity tests and optional multiplication steps, to ensure the production of reliable reference material. The flow chart was amended with a list of definitions describing the different terms related to reference materials and its

[6] EPPO, PM 7/84 (2) Basic requirements for quality management in plant pest diagnostic laboratories, Bulletin OEPP/EPPO Bulletin (2018) 48 (3), 378–386

production. In addition, the draft SOP contained an 'empty' SOP and an example of SOP for a particular plant pathogen (*Fusarium circinatum*) to exemplify the use and application of the SOP.

Following the completion of the first draft of the Standard Operating procedure (SOP) for the production of reference materials, this draft was circulated among the WP3 partners.

Initial comments on this first draft were used to finalise the draft SOP which was submitted as **D3.2 (Development of draft Standard Operating Procedures (SOPs) available for the production of the reference materials identified in Task 3.1**).

1.3.3.3 Task 3.3: Evaluation of guidelines and SOPs for the production of reference materials. (M8-M18). Leader: WR. Participants: NIB, NVWA.

The draft SOP (**D3.2**) was further evaluated by WP1 partners involved in the Test Performance Studies (TPS). In general this evaluation was positive and the resulting feedback was further analysed and summarised in a report (**M3.4: Report on the evaluation by WP1 (TPS organizers) of guidelines and the Standard Operating Procedures (SOPs) available**).

Responses on the draft SOP as reported on in **M3.4** were used to update and clarify definitions in the draft SOP and to further improve the general scheme of the SOP and the layout of the graphic representation of the SOP.

The final version of **D3.3. Guidelines and Standard Operating Procedures (SOP) finalised for the production of the reference material** describes the different steps required in the production process, ranging from the different possible sources of the reference material, tests to confirm its identity, possibly required multiplication steps to the actual production process. For each step in the process, criteria and critical points are identified. The criteria that reference material have to meet, and their minimum required levels are incorporated.

1.3.4 Work package 4

1.3.4.1 Task 4.1. Qualitative assessment of stakeholder requirements/demand (M1-M18). Leader: FERA Participants: all partners.

This task is designed to assess the demand for current and future tests and operating procedures. It ensures that stakeholder feedback is directly incorporated into the project, by forming the basis for the prioritisation of tests in Round 2 of the Test Performance Studies (TPS). Through incorporating elements of the multi-actor approach and co-design with end-users, this task supports plant health policies by ascertaining stakeholder views on attributes that lead to the adoption of surveillance and testing tools. The task was split into a number of milestones for drafting a stakeholder survey, identifying and applying prioritisation criteria. These have been delivered in close collaboration with scientific work packages; primarily WP1, with inputs from WPs 6 and 7.

Primary means of data collection were two online surveys hosted by the European and Mediterranean Plant Protection Organization (EPPO) and sent to laboratories registered in the EPPO diagnostic database and national plant protection organisations. The laboratory survey was designed in collaboration with work packages 1, 6 and 7, to ensure consistency and collect up-to-date validation data, as well as the Euphresco Virfast project, to minimise stakeholder fatigue. It consisted of 5 sections: (1) current testing priorities, (2) requirements for new or improved tests, (3) validation data, (4) the use of on-site testing kits, and (5) the use of High Throughput Sequencing technologies (HTS); for this task we were specifically interested in parts 1 and 3, as they directly informed the prioritisation process. In addition, EPPO designed a brief survey for national plant protection organisations, which asked representatives to rank their top 10 priority pests.

During initial discussions for the survey, it became clear that what work package 4 should provide is a list of pests, rather than tests, where tests are defined as the combination of pest, matrix and method. This has several reasons: first and foremost, the selection of tests is a complex process which needs to take into account a number of practicalities of organising a TPS, test context, as well as specific competencies of partner organisations. In addition, from a project point of view a certain breadth of organism types and other characteristics was required, as well as considerations whether other projects are already covering certain organisms; for example, a lot of work is currently done on *Xylella fastidiosa*. Therefore, a framework was created, which aggregated the ranked results from both surveys according to the priorities given by respondents. The combined ranking was then transformed into an interactive excel table, which included supplementary information on each pest's status, like whether it is currently a European priority (EU commission implementing decision 2018/2491), and whether respondents are using kits or on-site tests. This list was then handed over on to expert partners in WP1, who excluded pests already covered by other research or sufficiently validated. After adding additional high-priority pests, which are of interest due to their phytosanitary importance, WP1 partners volunteered for TPS organisation for those pests. Lastly, selected laboratories have identified methods and sample types and combined into a scope definition. With the help of WP2 recommendations, sample numbers were defined.

For more details on the prioritisation process see Figure 5 and **Deliverable 4.1**. **Report on stakeholder priorities for tests and general prioritisation framework.** After applying the framework to the long list of target pests obtained through the surveys, the selection for TPS organisers was the following: Arabis mosaic virus, *Cryphonectria parasitica*, *Melampsora medusa*, Plum pox virus, Tobacco ringspot virus, Tomato brown rugose fruit virus, Tomato ringspot virus, Tomato spotted wilt virus, *Xanthomonas citri pv citri*, *Xylophilus ampelinus*. Of those, the following have been selected: *Cryphonectria parasitica* (TPS organiser - UNITO), Tomato brown rugose fruit virus (TPS organiser - CREA), Plum pox virus (TPS organiser - ANSES), Tomato spotted wilt virus (TPS organiser - NIB), *Xanthomonas citri pv citri* (TPS organiser - ANSES), *Xylophilus ampelinus* (TPS organiser - Fera).

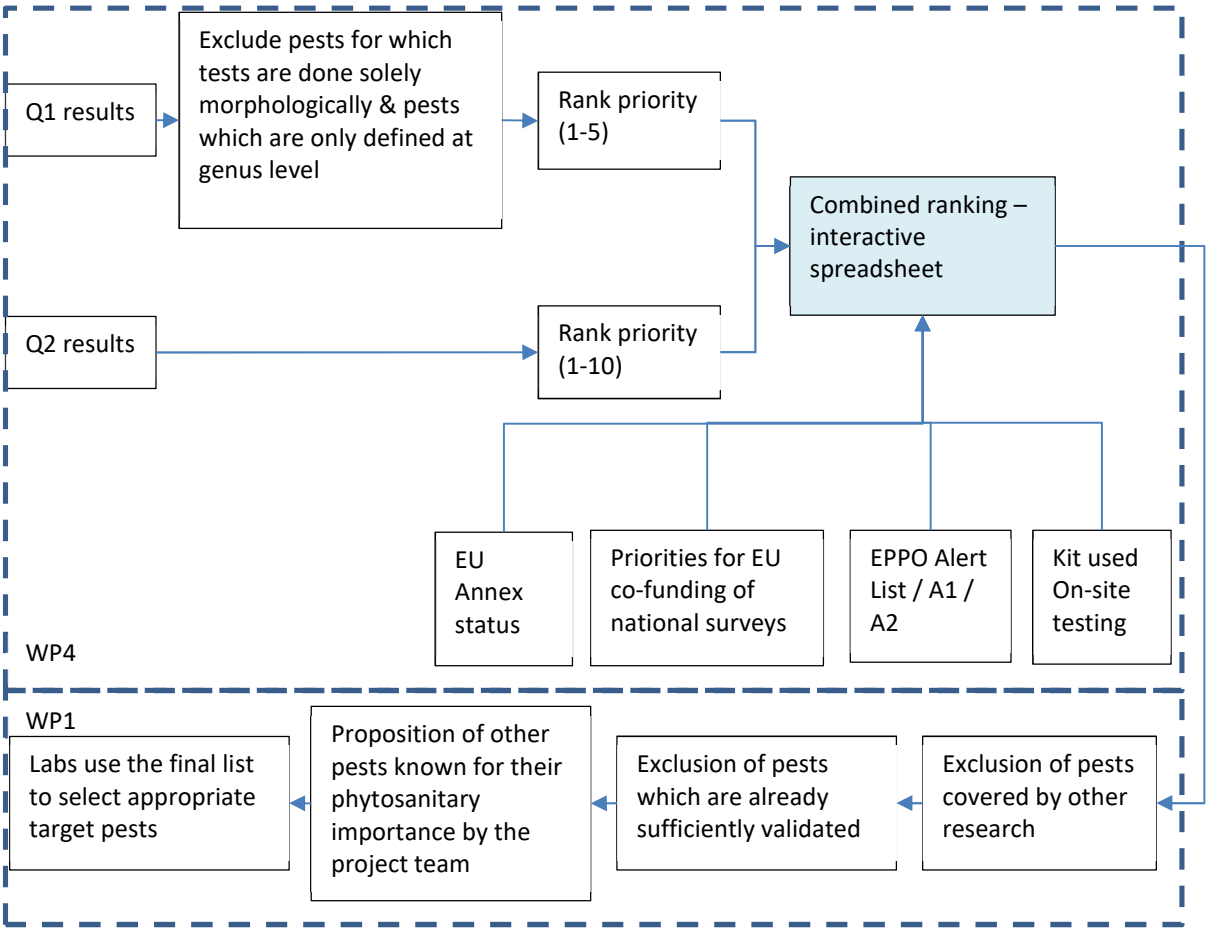

Figure 5. Prioritisation framework

1.3.4.2 Task 4.2. Impact assessment (M13-M34). Leader: FERA Participants: WBF, BIOREBA, EPPO, NIB, ULG, CD, WR, IPADLAB, SEDIAG, GIORIN.

This task has only just started. Initial discussions were held at the steering committee meeting in October 2019 and during a follow up discussion with partners from WP1, where it was decided that *Xylella fastidiosa* will be used as a case study for an impact assessment. Depending on time demands, other case studies may be selected at a later stage, where first priority will be given to *X. ampelinus* as a current major pest for trade of grapevine with third countries. High level data needs were identified, with the framework being defined in more detail over the coming months (**M4.5. Description of impact case studies and data needs available**).

1.3.5 Work package 5

1.3.5.1 Task 5.1. Identification of possible horizontal proficiency tests. (M12-M18). Leader: ANSES Participants: ANSES, WBF, EPPO, FERA, NIB, ULG, NVWA, CREA.

Work package 5 of the VALITEST project aims to develop guidelines on a horizontal approach allowing the laboratories to undertake proficiency testing (PT) without having to participate in proficiency tests for all the diagnostic tests they use.

During the reporting period, a range of data has been collected using three different methods:

i) Identification of the needs associated with the accreditation of laboratories through the analysis of the accreditation scopes of 24 laboratories. These accreditation scopes concern the laboratories listed in the EPPO database on diagnostic expertise[7] which have an accredited ISO quality assurance system and for which the accreditation scope could be retrieved.

ii) During the EPPO Workshop on quality assurance held in Paris in February 2019, a session dedicated to this work package of the VALITEST project took place. Attending experts were asked to work in subgroups and to brainstorm on the identification of critical points of proficiency tests and on the possible organisation of horizontal proficiency assessments.

iii) A survey on PT needs and potential PT features was sent to all the experts listed in the EPPO database on diagnostic expertise. The survey collected views from 22 experts working in 12 countries (Australia, Belgium, the Czech Republic, France, Germany, Ireland, Italy, the Netherlands, Slovenia, Spain, Switzerland and the United Kingdom).

According to the data collected the following conclusions could be drawn (**Deliverable 5.1. Analysis of the needs of the laboratories and applicability of the horizontal proficiency testing approach based on the questionnaire answers**). The appropriate length for conducting a PT plan (covering several disciplines, pests and diagnostic tests) is over 3 to 4 years. Each year a single PT should be organised per discipline. This PT can cover several pests as long as no more than 3 diagnostic tests have to be performed on a maximum of 10 samples. The PT should include whenever possible the different pests included in the scope of accreditation of the laboratories, but also emerging pests. For each discipline, priority pests have been identified. PT samples should be as similar as possible to routine samples and ideally different relevant matrices should be included in each PT. Among the different factors determining the reliability of a diagnostic test, the design of the PT plan should especially focus on human factors (i.e. the proficiency of the staff to use the different techniques). Laboratories do not wish to spend more than 3 500 € per year for a service providing several proficiency tests covering all their needs.

Based on these conclusions and on their knowledge of PT organisation, partners of the VALITEST project involved in WP5 will now develop guidelines on an approach to undertake horizontal proficiency testing (Deliverable D5.2) and consult accreditation bodies concerning the acceptability of the approach.

1.3.5.2 Task 5.2. Consultation of accreditation bodies. (M19-M21). Leader: EPPO Participants: EPPO, ANSES

Not applicable

1.3.5.3 Task 5.3: Preparation of guidelines (M19-M24). Leader: ANSES Participants: ANSES, WBF, EPPO, FERA, NIB, ULG, NVWA, CREA

Not applicable

[7] This database provides an inventory of the diagnostic expertise available in the EPPO region, it covers the expertise on regulated pests presenting a risk to EPPO member countries (http://dc.eppo.int/).

1.3.6 Work package 6

1.3.6.1 Task 6.1. Establishment and maintenance of a project website (M1-M36). Leader: EPPO Participants: all partners.

The website constitutes a key communication tool in order to increase the project visibility and to share knowledge and information about the project. It is the most important and immediate point of reference for all target audiences.

The structure and main content of the website were presented at the Kick-off meeting on the 31st of May 2018. All partners were asked to provide information on their institute/companies as well as on staff involved in the project to prepare the partners pages. WP leaders were asked to provide a short summary of their work package. The website was published at the end of July 2018 (Month M3) (**see deliverable 6.1. Project website and social media accounts**).

The VALITEST website Url is: https://www.valitest.eu/
It contains all relevant information about the project (project aims and objectives, information regarding the different work packages, information regarding the partners and advisory board, news and event announcements, publications and links with VALITEST social media). The website also hosts a reserved area dedicated to internal communication and a collaborative platform.
The website is regularly updated and improved with all the news about the project, including its outcomes, events, official articles and publications.
Since July 2018, more than 1600 users connected to the website from countries all around the world. Users visited on average around 5 pages per session. The most visited pages are related to the surveys organised during the project.

The VALITEST Twitter account (https://twitter.com/valitestproject) was created in May 2018. The latest news from the project and partners' participation in events are usually highlighted. In October 2019, the account is followed by 161 people and 78 tweets have been published.

1.3.6.2 Task 6.2. Development of a Dissemination and Training Plan (M1-M6). Leader: EPPO Participants: all partners.

The training and dissemination plan was prepared during the first six months of the project with the participation of all the partners of the consortium.
The different steps of the preparation are presented below:

- 2018-05-31: Presentation of the main sections and possible content of the dissemination and training plan (**M6.1. Draft dissemination and Training Plan presented**). The Management Board agreed that the document should be reviewed by the Steering Committee before being circulated to all partners.
- 2018-06-30: new version of the document circulated to the Steering Committee
- 2018-06-30 to 2018-07-25: gathering of first comments from the Steering Committee
- 2018-07-25 to 2018-09-07: second consultation of the Steering Committee
- 2018-09-07 & 2018-10-01: circulation of the Dissemination and Training Plan to all partners
- 2018-10-30: **deliverable 6.4. Dissemination and Training plan** finalised.

This document is intended to provide a guide to manage the different dissemination and training activities in order to engage the target audiences and to gain international visibility. It presents the objectives of training and dissemination activities which can be summarised as follows:
- Contributing to the wider harmonisation of the validation process
- Sharing validation data generated during the project
- Raising awareness and capacity building among stakeholders

- Enhancing product development by the diagnostics industry
- Increasing the project visibility
- Contributing to promote EU research.

Besides, different stakeholders have been identified as well as the key messages to deliver and the dissemination tools to be developed to that end.
Finally, this document also includes plans for internal communication between project partners.

The training and dissemination plan was submitted as a deliverable (**D6.4**). It was reviewed during the mid-term conference in October 2019 (see part 2 of this technical report for more details).

1.3.6.3 Task 6.3. Improvement of the validation section of the free access EPPO Database on diagnostic expertise (M2 – M24). Leader: EPPO Participants: all partners.

The EPPO Database on Diagnostic expertise (http://dc.eppo.int/index.php) includes a specific section on validation (http://dc.eppo.int/validationlist.php). Laboratories can deposit validation data that they have generated on specific tests and these can be made visible to all users of the database. The validation data can then be retrieved from the database in the form of a PDF file including the description of the test evaluated (pest x matrix x method) and the performance data related to the test (the information is presented in a harmonised format). There is currently no possibility to sort the data except by pest and method.

One of the objectives of VALITEST is to improve the searching capacity of the database to ensure optimal use. In order to evaluate the needs of users, a survey was organised at the end of 2018 (**see deliverable 6.2. Survey on the needs of users of the EPPO Database and exploitation of the data**). The questionnaire was elaborated by the EPPO Secretariat in collaboration with the different work packages leaders. The questionnaire was sent to the experts registered in the EPPO Database on diagnostic expertise (573 experts) and to industry contacts (20 contacts) in November 2018. Reminders were sent and the deadline was extended to the 15th of January 2019.
179 responses were received from 31 countries corresponding to an answer rate of 36%. This survey allows the identification of new features that need to be implemented in the validation section of the database such as:

- Allowing searches to be made on pests, methods, matrix and tests
- Allowing combined queries to be made as well as multiple pest queries
- Allowing a more in-depth sorting of information within molecular and serological methods
- Allow searches to be made on kits…

The IT developments necessary to include these new features are ongoing (**D6.6. Report on improved version of the validation section of the EPPO Database on diagnostic expertise, including new data provided by laboratories**)

In parallel of the improvement of the validation section, the Database on Diagnostic expertise will soon be transferred to a new redesigned and more user-friendly database. The visual layout of this redesigned database is similar to the one used for the VALITEST website in order to ensure the visual continuity with the project.

Finally, an inventory of the validation data available for the 6 pests included in the first round of test performance studies was performed (**D6.3. Inventory of validation data available**). From this work, some validation reports not available in the EPPO Database on Diagnostic expertise were shared by laboratories. Some of them were uploaded to the database and made available to the community.

1.3.6.4 Task 6.4. Dissemination to researchers, policy makers and other stakeholders (M8 – M36). Leader: UNITO Participants: all partners.

Recognition by the scientific community and end users of diagnostic tests is an essential step to increase

the credibility of the project results. Involvement of policy makers is also crucial to ensure that competent authorities and reference laboratories use the validated tests.
To this purpose, via different meetings organised by the partners or third parties, the objectives of the project have been presented to researchers (8 meetings including 2 research meetings/conferences, 5 EPPO panel on Diagnostic meetings and 1 workshop), policy makers (5 meetings) and official laboratories (1 meeting). Participation to these meetings was not funded by VALITEST apart from staff time.
The list of the meetings is available in the **milestone 6.4. Minutes of the meetings with policy makers and researchers**.

Besides, a factsheet, a flyer and a poster were designed to disseminate information on the project and to be used in meetings (**D6.5. Information materials (project fact-sheet, flyers, poster)**. Those documents are available on the VALITEST website.

1.3.6.5 Task 6.5. Dissemination/Training for diagnostics laboratories and NPPOs (M24 – M36). Leader: EPPO Participants: EPPO, ANSES, ULG, FERA, NIB, WR.

Not applicable for the reporting period

1.3.7 Work package 7

1.3.7.1 Task 7.1. Cooperation between SMEs and exploitation of results - Establishment of an EU Association of the Plant Health Diagnostics Industry. (M9-M36). Leader: IPADLAB Participants: WBF, BIOREBA, LOEWE, EPPO, NIB, ULG, ClearDetections, WR (Prime Diagnostics), IPADLAB, SEDIAG, GIORIN.

WP7 is dedicated to the promotion of the project's results and market exploitation. All SMEs of the consortium participate in this WP and the main objectives are the preparation of the foundations for an EU Association of the Plant Health Diagnostics Industry and an EU Plant Health Diagnostics Charter for Industry.
The aim of task 7.1 is to communicate on the advantages of validated tools in the project for the diagnostic chain in terms of sustainability to all the actors. The objective is the production of an exploitation plan that will help for the establishment of the EU Association of the Plant Health Industry. In this first period (M1-M18), the activities focused on the preparation of the initial exploitation strategy to better define actions plan (needs, objectives, role, timing,..) for the establishment of the EU Association of the Plant Health Industry.
The involvement of WP leaders has been crucial to define with partners the initial exploitation strategy for the main results coming from the project VALITEST. During the Steering Committee meeting that took place in April 2019, the exploitation definition, based on H2020 reference terms, was presented. This definition has been transferred also to all the WP7 partners. The companies participated, according to their availability, to the drafting of the exploitation plan.
One crucial point for the success of the exploitation plan is the definition of exploitable results. To reach this goal, two tables (Tables 5 and 6) have been sent to all WP leaders ("Expected results and exploitation routes" and "Expected results and intellectual property") to collect all the exploitable results available and expected in the framework of the project. These tables have been sent to all the WP leaders with all the explanations in order to help them to fill the tables.

Table 5. Template table for expected results and exploitation routes

N.	Project WP	Results expected and/or obtained	Expected date of the results	Who are the potential end-users?	Exploitation strategy	Actions to ensure the results exploitation	Protection
		Description of the expected and/or obtained results	*Indication of the expected date*	*List of the potential end-users*	*Indication of one or more option:* • *Use in further research activities* • *Developing, creating or marketing products* • *Creating and providing services* • *Use in standardisation activities*	*Indication of one or more option:* • *Regulatory affairs* • *Communication* • *Financial investments* • *Marketing strategy* • *Business plan*	*Yes or No*

Table 6. Template table for expected results and intellectual property

Project area	Results created	Involved Partner(s)	Access rights	Ownership	Protection (Yes/No)	Type of protection

In **deliverable 7.1**. **Results exploitation plan**, the first information collected from WP1, WP5 and WP6 are available and support the drafting of the deliverable 7.2. Communication and Exploitation strategy plans. The further development of D7.2 will also include the contribution of the other WP. In this first exploitation plan document, the strategy decided was to identify and define two general exploitation guidelines addressed to the two main groups of partners: industrial partners and research institutions partners. This approach is required because the exploitation strategy and the final exploitation plan objectives are very different between these two types of partners. The aim of these guidelines is to help

partners involved in the project to finalise a document that will describe their individual exploitation plan including all the needed actions. These two documents will be part of the exploitation plan.
The **deliverable 7.1** was delivered and it will have to be improved at months M24, M36 and the improvement shall be based on the consortium brainstorming sessions, considering possible changes, analysing the effective obtained results.
The exploitation and communication plan objective for the SMEs is to help in the establishment of the EU Association of the Plant Health Diagnostics Industry (EPDIA) of EU SMEs manufacturing diagnostic kits. In this period, benchmarking in other fields has been conducted and the information collected is under analysis in order to get information on what was already done in other fields. In particular, it has been identified, through some contacts with specialists from the veterinary sector, that producers of diagnostic kits for animal diseases are much further advanced with quality policy and standardisation. The strategy will be to use this already existing knowledge. All the documentation collected will be discussed within WP7 to better define the structure and the roles of EPDIA.
In the meantime, a questionnaire on the EPDIA establishment has been prepared by WP7 and it will be sent to all the VALITEST participants but also to several other actors (NPPO, private laboratories, research institutes, end-users of kits, accreditation bodies, inspection services, …) on the market (using the customers contact list of the companies and the contacts list of the VALITEST project partners) in order to receive suggestions from the market on the expected roles and structure of EPDIA. This questionnaire will be sent by the end of Month 22. The questionnaire is in a multiple-choice format and it must be filled in online. Only anonymised data are available for exploitation. The website used to collect answers to the questionnaire is committed to respect the GDPR rules. Hereunder an example of questions (for the whole questionnaire, please see **Appendix 2**):

European Plant Diagnostics Industry Association (EPDIA) establishment

The Mission 1/2

1. Please indicate your organisation activity

- ○ Laboratory performing official plant pest diagnostics
- ○ Private laboratory
- ○ Company manufacturing diagnostic kits
- ○ Other

2. According to you what would be the main mission(s) of the European Plant Diagnostics Industry Association (EPDIA)?

- ☐ To promote and develop phytodiagnostic technologies in Europe
- ☐ To represent the plant diagnostics Industry with European and International Institutions
- ☐ To develop the future of phytodiagnostic technologies
- ☐ To promote a Quality Charter for production and development of tools by plant diagnostics Industry
- ☐ To inform the market on phytodiagnostic technologies and validation

Other (indicate other proposals)

1.3.7.2 Task 7.2. Market exploitation strategy through the establishment of an EU Plant Health Diagnostics Charter for Industry. (M12- M36). Leader: IPADLAB Participants: WBF, BIOREBA, LOEWE, EPPO, NIB, ULG, ClearDetections, WR (Prime Diagnostics),, IPADLAB, SEDIAG, GIORIN.

During this first period of the project, WP7 partners and in particular the private companies, have been very active in understanding and participating in the organisation of TPS in the framework of WP1. Companies are not very used to TPS organisation and they usually only supply their reagents, under their commercial format. For this reason, this activity took a lot of work time from the companies. Since the beginning, some concerns were put forward by the companies with regards to the test selection procedure, the data validation, the protocols used and the results analysis and dissemination. For example, the validation data provided by the companies are often under their own format and they do not always match with the TPS organisers requirements. On the other hand, official institutions usually run TPS with the objective to obtain validation data with the constraint of limited budgets and this concern does not always match with the existing diversity in terms of reagents and protocols between the companies. For the first time in a TPS organisation, the VALITEST project has permitted dialogue between the TPS organisers and the TPS kits supplier companies and this had very positive results in term of understanding the needs and requests from each party taking in account the general goal of TPS. For companies, it is very important to understand how the TPS is organised and what information is needed from the TPS round 1 organisation in terms of technical and validation data.
Several conference calls have been organised within WP7 but also with WP1 in order to match the TPS1 organiser needs and companies' constraints:

- 28/08/2018: WP7 conference call on TPS participation
- 18/10/2018: WP1 and WP7 conference call on TPS1 organisation
- 12/12/2018: WP7 conference call on TPS 1 participation
- 19/02/2019: WP7 conference call on TPS 1 participation
- 04/07/2019: WP7 conference call on TPS organisation
- 22/07/2019: WP1 conference call on TPS2 organisation

Following these fruitful discussions, WP7 partners were involved in the preparation of a document describing and explaining the selection of tests for the first round of TPS and providing recommendations for test selection in the second round of TPS (details to be provided in deliverable 1.4. TPS reports with description of the method, materials and software used, as well as the data analysis - Round 1).
The results and experience gained from the first round of TPS will enable WP7 to identify the minimal validation data and quality requirements for commercial kits that are introduced on the market. Some discussions took place on how to bring together the companies' internal quality, validation and production procedures to the requirements of TPS organisers. This work will contribute to the finalisation of the EU Plant Health Diagnostics Charter for Industry (Deliverable 7.3. Definition of the EU Plant Health Diagnostics Charter for Industry) that will permit to companies to be more competitive and more reactive on the market.

1.3.7.3 Task 7.3. Organization of Dissemination/training workshops on the use of validated tools (M10-M36). Leader: IPADLAB Participants: BIOREBA, LOEWE, ClearDetections, IPADLAB, SEDIAG, WR (Prime Diagnostics).

A dissemination and training plan has been drafted (**milestone 7.1. Draft dissemination and Training Plan)**. The organisation of dissemination/training workshops is currently under preparation in tight relation with WP6. The training workshops will be organised in the second period of the project and the plans are in the process of reflection.
The companies of WP7 will conduct, in partnership with WP6, training workshops for diagnostic laboratories. At least three European workshops gathering VALITEST end-users from different sectors and countries will be organised towards the end of the project, one for Eastern/Central Europe in Poland, one

in Italy and one in the Netherlands. The companies will discuss and define the action plan of this training plan by month 24. This action plan will be available in deliverable 7.2 “Communication and Exploitation strategy plans”.
During the mid-term meeting, some important issues have been discussed on the planning of these workshops and in the first quarter of 2020, meetings will be organised in order to finalise the planning.

1.3.8 Work package 8

During the first reporting period M1-M18, the VALITEST project management bodies and procedures were created and started to work. The coordination team was established and includes the coordinator and his deputy, a project manager and administrative support from the ANSES European and International Affairs Department. The coordination team ensures the day-to-day management of the project, including scientific, administrative and financial aspects. All partners are involved in WP8.

1.3.8.1 Task 8.1. Organisation of project management meetings. (M1-M36). Participants: all partners

All the meetings planned during the reporting period M1-M18 (**milestones 8.1 to 8.6**) were organised either as conference calls or as physical meetings (Table 7).

Table 7. Meetings of the VALITEST project

Meeting	Foreseen month	Delivery date	Location
M8.1. Kick off meeting + SC meeting 1	M1 (May 2018)	31 May 2018 & 1 June 2018	Maisons Alfort (France)(1)
M8.2. SC meeting 2	M4 (August 2018)	7 September 2018	Conference call
M8.3. SC meeting 3	M8 (December 2018)	14 December 2018	Ljubljana (Slovenia)(1)
M8.4. SC meeting 4	M12 (April 2019)	5 April 2019	Conference call
M8.5. SC meeting 5	M16 (August 2019)	4 September 2019	Conference call
M8.6. Mid-term general assembly	M18 (October 2019)	1&2 October 2019	Rome (Italy)(1)

(1) physical meetings

The coordination team provided logistic support for the preparation of these meetings and chaired the meetings.

The management board members have been regularly informed about the VALITEST progress. They participated in the kick-off meeting in Paris in May 2018 and in the mid-term meeting in Rome in October 2019. During this last meeting, they reviewed the progress of the project and had the opportunity to comment on each task of each work package. Their inputs are reported in the meetings minutes.

A steering committee (SC) meeting was organised every 4 months to monitor the progress of the project. During these meetings, each WP leader presented an activity report on the implementation of their WP work compared to the objectives and deadlines set.

The advisory board members were appointed between December 2018 and April 2019. The final list is composed of four internationally renowned scientists (Maaike Bruinsma and deputy Hubert Lybert (ISHI-Veg), Adriana Moreira (IPPC Secretariat), Neil Boonham (Newcastle University) and Mark Nakhla (USDA APHIS)). The VALITEST webpage dedicated to the advisory board (https://www.valitest.eu/partners/advisory_board) includes a short biography of each member of the advisory board. The advisory board members are regularly informed about the progress of the VALITEST project. Since the SC3 meeting in December 2018, the appointed members of the advisory board have either attended VALITEST meetings or, if not available, have received all relevant documents (agenda, progress reports…) and their inputs are reported in the minutes of the meetings.

1.3.8.2 Task 8.2. Scientific coordination. (M1-M36). Participants: ANSES

The coordination team supervised the preparation of the deliverables and milestones for the reporting period M1-M18 and has submitted the deliverables to the EC. The coordination team provided templates for deliverables and for reporting (e.g. WP activity report presentation) in order to ensure the consistency and harmonisation of the work. All templates are available on a dedicated and restricted area of the EPPO extranet. The coordination team has ensured the conformity of the deliverables produced by the different WPs with the assigned objectives. Before submission on the H2020 portal, the steering committee reviewed, commented and validated the deliverables. All the finalised deliverables are available on a dedicated and restricted area of the EPPO extranet.

The coordination team monitors the progress of the project. All the deliverables and milestones have been achieved and submitted. For delivery delays of the deliverables beyond two months of the defined deadline, explanations and justifications are indicated in the section 1.1.1.

During the mid-term meeting in October 2019, the coordination team presented a schedule for the preparation of the periodic reports in order to help the management board finalise them in due time (**deliverable 8.2. Periodic report**). Moreover, the coordination team explained in details how to fill in the technical and financial reports and prepared guidelines (e.g. technical report template, notes on rules to calculate and declare costs, financial reporting procedure), all made available on the EPPO extranet.

Communication tools (VALITEST website, twitter account, extranet), regular call conferences between the coordination team and WP leaders and email exchanges, ensure effective communication within the consortium.

1.3.8.3 Task 8.3. Overall contractual, ethical, financial and administrative project management. (M1-M36). Participants: ANSES

The coordination team managed all financial, legal, contractual and administrative aspects of the project for the considered reporting period and has ensured that the partners apply the procedures described in the Grant Agreement and in the Consortium Agreement.

The coordination team prepared **deliverable 8.1. Data Management Plan (DMP)** describing the data management's life cycle for the data to be collected, processed and/or generated by the project. Data management follows the FAIR principle (findable, accessible, interoperable and reusable). All the partners are responsible of the security of the data they collect, process or generate. Any breach in the security has to be reported immediately to the coordination team. If the breach is likely to result in a high risk of adversely affecting individuals' rights and freedoms, the breach will be reported to the relevant supervisory authority and the affected individuals (**D9.1. Protection of Personal Data**).

Data Management Plan was revised at mid-term (**deliverable 8.3. Data Management Plan first revision**). The revision of the data management plan is detailed in section 3.

By default, the data and metadata of VALITEST will be made openly available. However, in some cases open access can be incompatible with rules on protecting personal data: protection of the individual right have to be ascertained either by avoiding open access to sensitive and personal data, or by anonymising the data. **Deliverable 9.1** (confidential) specifies the procedures implemented for personal data collection, storage, protection, retention and destruction.

All the VALITEST partners' contacts have signed an "Authorisation for the recording and use of participant images, slides and professional data". The list of the VALITEST partners contacts with the details of each mailing list per WP is available on the dedicated and restricted area on the EPPO extranet.

In order to allow the advisory board to carry out its task and provide advice to the project to help achieve its impacts and objectives, and to respect the confidentiality rules, the DoA (Description of Action) has

been provided to the advisory board members under a confidentiality agreement. A specific directory (team VALITEST – Advisory Board) has been created in the dedicated and restricted area of the EPPO extranet with access to deliverables and meeting reports and minutes for advisory board members only.

The coordination team also prepared a first amendment to the VALITEST Grant Agreement which includes three modifications of the WP1 budget and description of work:

- Modification of the allocation of the resources and the description of the content of the 2nd round of TPS, following the choice of target pests for the 2nd round of TPS, decided after the implementation of a survey by WP4 (**M4.3 - Completion of survey and application of prioritisation criteria**). The detailed description of the content of the 2nd round of TPS and the allocation of the budget to the partners involved are included in Part B of the amended Grant agreement.
- Modification concerning future involvement of NVWA in WP1 coordination: following the withdrawal of NVWA from the overall coordination of WP1 in April 2019, due to the absence of the WP1 co-leader, it was decided to strengthen the position of NIB as WP1 leader and to appoint ANSES to support them as WP1 co-leader.
- Modification of the estimated delivery date for deliverable 1.3. List of tests for validation - Round 2 from 30 September 2019 (M17) to 31 December 2019 (M20), as the TPS organisers need additional time to perform preliminary in-house assessments to select the final tests for the second round of TPS.

The first amendment to the Grant agreement was validated by the European Commission on 8th August 2019.

Regarding the financial management of the project, ANSES as coordinator received the pre-financing payment from the European Commission at the beginning of the project (May 2018) and transferred the amounts due to the partners in June 2018 according to the VALITEST internal payment strategy, defined in the Consortium Agreement. According to this strategy, a second pre-financing payment was transferred to the partners involved in the 2nd round of TPS in October 2019, following the validation of the first amendment to the Grant agreement and the modification of the budget allocated for the 2nd round of TPS.

1.3.9 Work package 9

1.3.9.1 D9.1. POPD (Protection of Personal Data)– Requirement n°1

This deliverable describes the data management life cycle for all sensitive data to be collected, processed and/or generated during and after the VALITEST project. Data managers have been appointed by each partner and procedures have been defined to comply with General Data Protection Regulation (GDPR, Regulation (EU) 2016/679), which is applicable since May 2018.

Deliverable D9.1 was slightly delayed from October 2018 to December 2018 without any impact on the project. Personal data protection is a new requirement for most partners (including the project leader) for which additional time to ensure correct understanding and application of the requirements was needed.

1.3.9.2 D9.2. NEC (Non European Countries)– Requirement n°2

This deliverable describes the relations between the consortium and the non-EU countries. During the preparation of this deliverable, the Ethics part of the H2020 online manual and the Access and Benefit Sharing (ABS) Regulation's scope were studied. Experts on the subject (from ANSES) were contacted to define the rules for exportation and importation of biological material from and to the EU.

Deliverable D9.2 was delayed from July 2018 to February 2019 without any impact on the project. This delay was due to the fact that **deliverables D9.1** (POPD) and **D8.1** (DMP) had to be finalised before drafting of **deliverable D9.2.**

1.4 Impact

The different impacts described in the DoA are still relevant and do not need to be updated.

In the framework of the progress of the project, we can already identify how the project contributes to some of the described impacts. The following elements provide relevant examples from outcomes of the project in relation with specific impacts:

Validated tests for the detection of pests: at the end of the mid-term period, the first round of TPS led to the evaluation of 42 tests, for some of which validation data will be included in relevant regional diagnostic protocols.

Support for plant health policies in the form of validated tests to be used by competent authorities and reference laboratories: the second round of TPS includes pests with current high interest for the competent authorities and reference laboratories, the Tomato brown rugose fruit virus (ToBRFV), a major emerging threat for tomato seeds trade, and *Xylophilus ampelinus*, a bacteria that complicates the export of vine plants from the EU region to third countries.

Support the improvement of plant health and food safety, thus contributing to the sustainability and competitiveness of the agri-food sectors: in both rounds of TPS, on site technologies, i.e. LAMP tests, were included for validation. This technology has a great potential for quick analysis and results in various situations. The project will already provide guidance and validation data for a LAMP test for the detection of *Bursaphelenchus xylophilus*, the pinewood nematode.

Strengthening the competitiveness and growth of companies: from the first round of TPS, for some commercial kits, clues for improving the performance of the reagents were identified, in order to better answer the needs of the final users.

2 Update of the plan for exploitation and dissemination of results

The training and dissemination plan presents the objectives of the training and disseminations activities organised within the framework of the VALITEST project as well as the tools provided to ensure that the objectives will be met (see section 1.3.6.2).

The training and dissemination plan was submitted as a deliverable on the 30th of October 2018 (Month M6) (**deliverable 6.4**). It was reviewed and revised during the mid-term conference in October 2019. In particular, the modalities to inform the partners about intentions to disseminate results through participation to external events have been revised. From now on, an advance notification to the Management Board of 20 days (instead of 45) should be done by email to a specific list of partners contacts before registration or submission of an abstract. Besides, a partner can object within 10 days (instead of 30) after receiving the notification.
The strategy regarding the dissemination of the Test Performance Studies (TPS) results has been added to the dissemination plan. By default, the names of all the tests and the associated validation data can be used for dissemination activities. However, before any dissemination of TPS results including tests using commercial kits, a teleconference has to be organised by the coordination team. The relevant commercial partners from WP7 are invited to these meetings so they can discuss the results of the TPS with the TPS organisers. During these meetings, they can oppose the dissemination of the name of their kits and/or of the associated validation data. Summary reports of the TPS results (e.g. power point presentations) will be sent to the commercial partners at least 2 weeks before the meeting.
Several other minor changes regarding the update of the website, mailing lists and contact points have also been made.

The aim of the exploitation plan in VALITEST project is to ensure the sustainability of the project's results beyond the end of the project and to demonstrate how VALITEST could influence EU plant health diagnostic field. Following the organisation of the first round of TPS and the achievement of the first results, **deliverable 7.1** will have to be updated by month 24. In the second period of the project, companies will be actively involved in defining new strategies on commercial kit validation and quality production. **Deliverable 7.1** will be updated and these results will be available in deliverable 7.2. Communication and Exploitation strategy plans.

During the midterm conference, the partners discussed the organisation of the training workshops in collaboration with WP6 (**milestone 7.1**). The reflections are in progress and meetings will be organised between WP6 and WP7 in the first quarter of 2020 to better define the training workshops organisation. Concerning WP7, the companies have already decided that the selection of kits presented in these training workshops will depend on the results of the first round of TPS.

3 Update of the data management plan

The DMP has been revised at mid-term month M18 (**deliverable 8.3**) following decisions taken by the SC during the first period of the project and by the MB during the mid-term meeting in October 2019.

Since open access data may compromise the quality trademark of partners. It had first been decided that only the name of the best performing kit(s) would be made available and that the performance characteristics of marketed tools providing unsatisfactory performance levels would be systematically anonymised before being made available. Given the sensitivity of the subject, many discussions took place within WP7 and WP1. It was decided that the disclosure of the performance of the various tests would be discussed on a case-by-case basis by WP1 leaders and kit providers from the project consortium. The DMP has been updated to take this decision into account (§2.2.1).

During the mid term meeting, the management board agreed on a two-step process to decide wether or not deliverables should be made freely available (i.e. uploaded on a repository with links on the VALITEST website):

- Each WP leader should seek agreement within the WP on which deliverables should be made freely available.
- During the Steering Committee (SC) (or by e-mail if necessary), the work package leader informs the SC of the proposal of the work package partners to make the deliverables freely available or not. The SC takes the final decision

The DMP has been modified accordingly (§2.2.2).

During the mid term meeting, the MB agreed on the use of DROP (Digital Repository Object Portal, a platform designed in the framework of the EU project XFACTOR) as a portal and of Zenodo as a repository. Each time a partner will share data in Zenodo, he will have to inform WP6 by email and WP6 will ensure the DROP posting. The DMP has been modified accordingly (§2.1.1; §2.2.2; §2.2.4)).

Concerning ethical aspects, the new version of the DMP clarifies that no difference of data management will be made between data generated or provided by subjects located in the EU or in third countries (§5).

4 Follow-up of recommendations and comments from previous review(s)

Not applicable, as the first review of VALITEST has not taken place yet.

5 Deviations from Annex 1 and Annex 2

5.1 Tasks

No major deviations affecting the progress of the project and its expected impacts have arisen although the delayed start date of the project (from January 2018 to May 2018) had an impact on the ability of the partners to respect the planned timeline. Indeed, the project started in May just before the summer period, with limited availability of staff during this period. One other difficulty the project management had to face was the withdrawal of the partner NVWA from the overall coordination of WP1. Despite these difficulties, achievement of the objectives of the project is still on track and the consortium made an important effort to catch up and ensure that all tasks are up to date at the time of submission of this report. The management of the project paid special attention to interdependencies between tasks and no task was impacted because of a delayed milestone or deliverable.

5.2 Use of resources

During the 1st reporting period M1 – M18, on the project level, the resources (PMs and budget) were used as estimated, with a slight underspending: the execution rate of the project for the period is 83.6% for the person months and 80.7% with regards to the budget (Table 8). The slight deviation is mainly linked to the fact that some activities started later than expected and will be implemented or finalized during the 2nd reporting period.

Table 8. VALITEST total resources consumption M1 – M18

Reporting period	**Estimated PMs**	**Real PMs**	**Deviation**	**Execution rate**
M1 - M18	187.57	156.72	-30.84	83.6%
Reporting period	**Estimated €**	**Real €**	**Deviation**	**Execution rate**
M1 - M18	1 426 313.60	1 150 850.93	-275 462.66	80.7%

Regarding the use of resources per WPs (both PM and budget), four WPs (WP1, WP2, WP3 and WP8) implemented their budget and staff efforts as planned or with a slight deviation. The underspending for the four remaining WPs (WP4, WP5, WP6 and WP7) is more important (Figures 6 and 7). The deviation is explained by the fact that the activities of these WPs will be mainly implemented during the second period of the project, while the distribution of the resources per reporting period is quite linear. In addition, as mentionned above, some difficulties were faced at the very beginning of the project, due to the delayed start date (May instead of January) and also to recruitement issues or strategies for some partners. For WP4 and WP7, the use of PMs is more important than the budget spending. These deviations can be explained on a partner per partner level. Most of the partners have slightly underspent their budget, though for some others, the underspending is quite significant. This can for instance be explained by the fact that some persons who carried out the work during the period had a lower hourly rate than that used for the estimation, or the fact that one partners (3-WBF) decided not to declare personnel costs during this first reporting period, while still performing the work as expected in order to be able to be involved more actively and recruit a person full time on the 2nd round of TPS.

Nevertheless, the resources remaining from this first period are expected to be used during the second

period when the activitities of the four WPs will continue their progress. The coordination team closely monitors the use of resources and will ensure both the completion of the tasks announced and the proper use of the resources allocated.

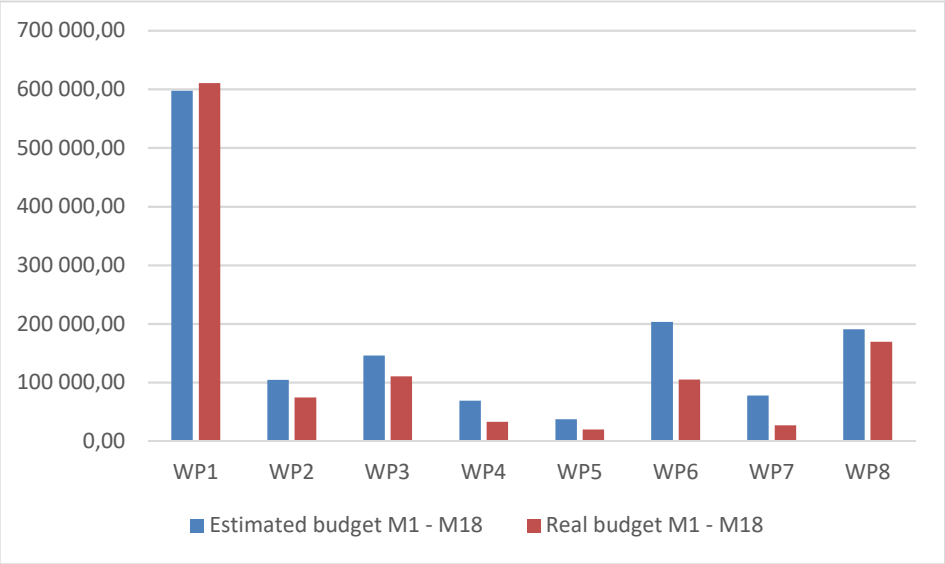

Figure 6. Budget in euros (EU contribution) per WP (M1 – M18)

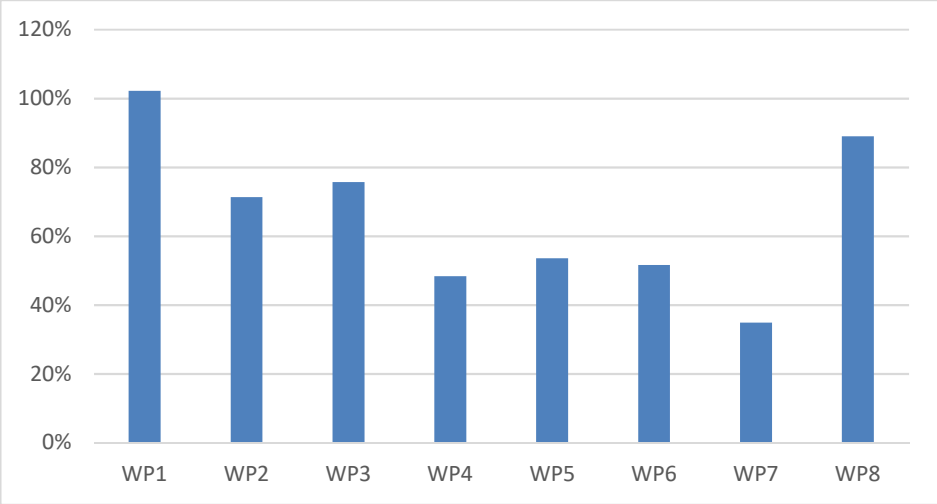

Figure 7. PM execution rate by WP (M1 – M18)

Since the start of the project, the coordination team ensures open discussions with each partner on their capacities to perfom their tasks as planned and on the required resources to ensure the project activities progress as planned and within the frame of the planned resources and can propose relevant reallocation of resources when required.

Include explanations on transfer of costs categories (not applicable).

Include explanations on adjustments to previous financial statements (not applicable).

5.3 Unforeseen subcontracting (if applicable)

Not applicable

5.4 Unforeseen use of in kind contribution from third party against payment or free of charges (if applicable)

Not applicable

Appendix 1. TPS Participant contract (example for *Pantoea stewartii* subsp. *stewartii*)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 773139

Test Performance Study (TPS)
Participant's contract

To register to the TPS (Test Performance Study)
please, fill in this form and return it signed by email:
niblabfito@nib.si; niblabfito@gmail.com

TPS code	**Pstew-1**
Scope of TPS	**Molecular detection of *Pantoea stewartii* subsp. *stewartii* in asymptomatic plant material (maize seeds)**

LABORATORY	
Name	
Delivery address	
Telephone	
Fax	
Email	

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Registration

The laboratory agrees to participate in the TPS: ☐ Yes [1]

(1) By validating its registration, the laboratory identified on the first page of the contract (further mentioned just as "participating laboratory") agrees to participate in the TPS organised by National Institute of Biology, Department of Biotechnology and Systems Biology in the conditions of participation described below

Please provide all the information requested in the table below:

<table>
<tr><td>Communication</td><td>1) Identify a TPS correspondent of your laboratory :
First name / Last name: .....
Function: .....

2) Provide two valid electronic addresses (different persons) for the transmission of the results and for exchanges with the organiser :
.....
.....</td></tr>
<tr><td>Analytical tests to be evaluated</td><td>3) Select the tests that will be tested in your facilities :

Tests for Pantoea stewartii subsp. stewartii
precise the tests to be evaluated by ticking the relevant box (for the benefit of the project and in order to get enough data, the participant is invited to evaluate all the tests related to the methods it is willing to perform[2])
<table><tr><th>☐ Tests to be evaluated – real-time PCR</th><th>☐ Tests to be evaluated - PCR</th></tr><tr><td>• Tambong et al., 2008 (Journal of Applied Microbiology 104, 1525–1537) adapted from the original publication.
• Thwaites et al. (FERA protocol, EUPH05 Pantoea stewartii subsp. stewartii Final Report)
• Wensing et al., 2010 (Applied and Environmental Microbiology, 76:6248-6256) adapted from the original publication.
• Pal et al. (Plant Disease, accepted for publication) adapted from the original publication.</td><td>• AGES, 2016 (EPPO Bulletin 46 (2): 226-236) adapted from the original publication.
• Gehring et al., 2014 (Journal of Applied Microbiology 116: 1553-1562) (galE locus) adapted from the original publication.</td></tr></table>
[2] The participating laboratory will have to apply the detailed protocol of each test provided as appendices of the technical sheet. These protocols are adapted from EPPO, IPPC, the original publications or refer to manufacturer's instructions

Any comments: .....</td></tr>
</table>

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Requirements

4) Specify the regulatory status of samples with pest to be dispatched (alive pest or infectious material):

Test items (samples) and controls will be thermally inactivated and will not contain live target pathogens. A panel will contain 20 test items (plant extracts) and controls of 200 µL each. All will be provided in 1,5 mL micro-centrifuge tubes.

Tube	ID	Type	Volume [µL]
1	Sample Pstew-M1	test item (plant extract)	200
2	Sample Pstew-M2	test item (plant extract)	200
3	Sample Pstew-M3	test item (plant extract)	200
4	Sample Pstew-M4	test item (plant extract)	200
5	Sample Pstew-M5	test item (plant extract)	200
6	Sample Pstew-M6	test item (plant extract)	200
7	Sample Pstew-M7	test item (plant extract)	200
8	Sample Pstew-M8	test item (plant extract)	200
9	Sample Pstew-M9	test item (plant extract)	200
10	Sample Pstew-M10	test item (plant extract)	200
11	Sample Pstew-M11	test item (plant extract)	200
12	Sample Pstew-M12	test item (plant extract)	200
13	Sample Pstew-M13	test item (plant extract)	200
14	Sample Pstew-M14	test item (plant extract)	200
15	Sample Pstew-M15	test item (plant extract)	200
16	Sample Pstew-M16	test item (plant extract)	200
17	Sample Pstew-M17	test item (plant extract)	200
18	Sample Pstew-M18	test item (plant extract)	200
19	Sample Pstew-M19	test item (plant extract)	200
20	Sample Pstew-M20	test item (plant extract)	200
21	Pstew-M-PIC1	control (plant extract)	200
22	Pstew-M-PIC2	control (plant extract)	200
23	Pstew-M-NIC1	control (molecular grade water)	200
24	Pstew-M-NIC2	control (molecular grade water)	200
25	Pstew-M-PAC1	control (DNA of the target organism)	200
26	Pstew-M-PAC2	control (DNA of the target organism)	200
27	Pstew-NAC	control (molecular grade water)	200

5) Regulatory requirements concerning the plant health regulatory of your country (territory) to allow the sending of the samples:

☐ No requirements

☐ Requirements[3]:

☐ the parcel must be accompanied by a LOA[4]

☐ other: precise: .....

[3] **IMPORTANT**, if requirements are specified and if the TPS organizer doesn't have the necessary documents before the date set for sending the samples, the legislation will not

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	allow to send the parcel of samples and the participation of the laboratory will be compromised. (4) Letter of Authority authorising the circulation of a regulated pest in the European Union. **6) Samples reception requirements** **The samples will be dispatched in weeks of March 25th to April 5th 2019.** The participating laboratory will be available to receive the samples during this period: ☐ Yes ☐ No[5] (5) If no, the participating laboratory has to inform imperatively the TPS organizer by email: niblabfito@nib.si; niblabfito@gmail.com.

Conditions of participation

Implementation of the TPS:

The participating laboratory agrees to perform analyses in its laboratory according to the instructions of the TPS organizer (the instruction sheet will be sent together with the panel of samples), and in its usual conditions of work.

Any modification should be reported to the TPS organizer. This kind of information can be very important for the interpretation of results.

The participating laboratory commits to communicate about any difficulties encountered during the implementation of the TPS.

The participating laboratory commits to provide all results on the result form provided to it within the deadline indicated on the TPS technical sheet.

Transmission of the results

The TPS report will be transmitted to each participating laboratory in electronic format.

Concerning the dematerialisation of the proficiency testing report, the following convention of proof applies.

The TPS report is transmitted in a protected pdf format attached to an e-mail sent to the two electronic addresses communicated in writing by the participating laboratory in the participant's contract. The signatures of the authorised persons on the first page of the proficiency testing report constitute proof of its validation and its authenticity.

The TPS organizer keeps the original file (electronic version and paper version) and also the evidence of its authenticity which could be used in the event of litigation.

Moreover, the participating laboratory:

-commits to not modify this file;

-is informed that the paper editions from the transmitted pdf file are under its sole responsibility;

-recognises the validity and the convincing strength of this file.

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Confidentiality and collusion

The TPS organizer will provide each participating laboratory with a panel of coded samples. Coding of the samples will be kept confidential by the TPS organizer until the end of the TPS.

Each participating laboratory commits to not communicate with other participants or any third parties regarding the samples or any part of the results.

The participating laboratories are informed that the TPS results will be analyzed anonymously and then each participating laboratories will get its own results.

The participating laboratory is informed that the TPS results could be used anonymously for scientific purposes. The participating laboratory would be associated to the results exploitation. The participating laboratory is not allowed to publish its results in any kind of format or by any mean.

The TPS organizer is committed to securing your information, keeping it strictly confidential and not sharing it with any other company or other third party.

The participating laboratory agrees to the handling of its data for the purposes of the TPS in accordance with the General Data Protection Regulation (GDPR). The way in which its data is used for the purposes of the TPS is described in the Appendix.

Confinement

The participating laboratory must have adopted measures to prevent the risk of unintentional release of plant pests for which it is approved (containment, processing of waste, etc.).

The participating laboratory commits to inform the TPS organizer in the TPS participant's contract of the plant health regulatory requirements of its country (territory), in order to allow the sending of the samples in conformity with its regulatory. The participating laboratory also commits to complete the necessary formalities to allow the receipt of the samples and so to ensure its participation in the TPS.

Samples sent by the TPS organizer must be used only in the framework of the VALITEST project activities. The participants may use the provided extra material to assess other DNA isolation methods and/or modifications of tests provided the results are reported to the TPS organiser and made available to the Valitest project in the same manner as other TPS results.

The TPS organizer declines any responsibility for the use of the samples or any remainder outside the framework of the VALITEST project activities.

Name and function: **Date:** **Signature:**

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Appendix: GDPR Disclaimer

Categories of personal data

Your consent to the processing of personal data is freely given. By registering, you agree that National Institute of Biology (NIB) will process the following personal data for the purposes of this consent form: title, name, surname, address, e-mail address and your consent to the processing.

Safety of important personal data

NIB will carry out appropriate technical and organizational measures designed to protect your important personal information.

Retention of the personal data

NIB may store your personal data for as long as necessary for the purposes for which the personal data are processed, or for such a long time and for such purposes as required or permitted by applicable law. After this period, NIB will immediately delete or render your personal data anonymous.

Your rights

In accordance with applicable law (including exceptions or derogations from this legislation), you have the right to request access to your personal data as well as its rectification, removal or restriction of processing, the right to object to the processing, the right to transfer data, the right to withdraw consent for the processing of personal data for a specific purpose, if such consent has been previously given, the right to bring a complaint to the supervisory authority in connection with the processing of personal data. Any request has to be notified by email (niblabfito@nib.si; niblabfito@gmail.com).

Applicable law

This form is subject to the legislation of the EU and is interpreted in accordance with it. This does not affect your legal rights.

Appendix 2. Draft questionnaire for the establishment of a European Plant Diagnostics Industry Association

European Plant Diagnostics Industry Association (EPDIA) establishment

The Mission 1/2

1. Please indicate your organisation activity

- ○ Laboratory performing official plant pest diagnostics
- ○ Private laboratory
- ○ Company manufacturing diagnostic kits
- ○ Other

2. According to you what would be the main mission(s) of the European Plant Diagnostics Industry Association (EPDIA)?

- ☐ To promote and develop phytodiagnostic technologies in Europe
- ☐ To promote a Quality Charter for production and development of tools by plant diagnostics industry
- ☐ To represent the plant diagnostics industry with European and International institutions
- ☐ To inform the market on phytodiagnostic technologies and validation
- ☐ To develop the future of phytodiagnostic technologies

Other (indicate other proposals)

Mission 2/2

3. If you think that the EPDIA's role is to represent the Plant Diagnostics Industry with European and International Institutions, what would be the main task(s)? (please rank from the most important (1) to the less important (5))

- To define and advocate the common interests, policies and positions of the European Phytodiagnostic Industry
- To establish and reinforce the link with European Institutions and NPPO in order to improve the quality and performance of the tools offered to the market by the plant diagnostics industry (TPS, transfer of validation data, standardization of validation methods, etc.)
- To share with European institutions and stakeholders on the needs and / or difficulties of end-users in the use of reliable, validated and qualitative phytodiagnostics tools
- To engage in dialogue with the European institutions and other stakeholders in order to advance understanding of industry-related issues at both European and global levels
- To interact with the European institutions and other stakeholders in order to contribute to effective policy, legislation and regulation at the European level

4. If you think that EPDIA's role is to promote and develop the use of high quality phytodiagnostic products in Europe, what tools could it use?

- ☐ Website
- ☐ Workshop and education programms
- ☐ Organisation of TPS
- ☐ Publications
- ☐ Fairs
- ☐ Other (please indicate other proposals)

Members

5. What should be the profile of the potential members?

- ☐ Manufacturer SMEs
- ☐ Private laboratories
- ☐ Research institutions
- ☐ European organisations or institutions
- ☐ Universities
- ☐ Others

Structure of the Association

6. Under which form could the association be organised?

- [ ] A website managed by the members (where you can get informations, news, promotions on the Plant Health Industry)
- [ ] A real association (with charter, working groups, comittees, board of directors,..)
- [ ] A working group with a website
- [ ] Others

7. What kind of membership would you expect in such an Association?

- ◯ Payment of the membership
- ◯ For free
- ◯ Others

8. How the potential member could join?

- ◯ Simple form
- ◯ Membership request evaluated and validated by a committee
- ◯ Others

9. What would you suggest to finance the Association?

10. Please indicate other suggestion for the EPDIA establishment