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VALITEST: Validation of diagnostic tests to support plant health

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VALITEST is an EU-funded project built to improve the reliability of diagnostic tests performed in plant health laboratories across the European and Mediterranean region. The project is undertaken by a consortium of 16 partners composed of research institutions, private companies (such as diagnostic kit providers), national plant protection organizations and one intergovernmental organization (EPPO). Current harmonized procedures for the validation and organization of test performance studies will be improved based on the experience gained from the project and by including appropriate statistical approaches, by adapting the process for new promising technologies (e.g. high-throughput sequencing) and by providing new guidelines for the production of reference materials for validation studies. The project will provide a more complete and precise description of the performance of 82 diagnostic tests targeting 11 pests of interest for stakeholders of the region. It will also tackle the need for proficient users by developing a horizontal approach for the evaluation of laboratories' proficiency and by organizing training activities on the concept of validation. The outcomes of the project will stimulate, optimize and strengthen the interactions between stakeholders in plant health for better diagnostics and lay the foundations for structuring the quality and the commercial offers for plant health diagnostics tools thanks to the creation of a dedicated association and a quality charter.

Background

Up to a quarter of the world's crops are lost to pests, causing major economic losses and social impacts globally. Protecting crops against these losses from farm to fork is critical for achieving sustainable and competitive agriculture as well as for the protection of biodiversity and ecosystems. Establishing smart surveillance mechanisms is essential for the fulfilment of this important goal as it enables effective monitoring and control of the introduction and spread of plant pests (Carvajal-Yepes *et al.,* 2019).

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

Validation is an essential process to provide information on the performance of the tests that are used in diagnostics and to ensure the reliability of the diagnostic activity (Fig. 1A). It consists of the evaluation of different performance criteria such as analytical sensitivity, analytical specificity, selectivity, repeatability and reproducibility (EPPO, 2019, 2018). 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 harmonize procedures across the EPPO region. This involves the preparation of pest-specific diagnostic protocols, as well as horizontal Standards providing guidance on the validation of tests or on the performance of interlaboratory comparisons. Although the situation is currently evolving, performing validation still mainly relies on initiatives from individual laboratories and tests are currently mostly validated on an intralaboratory basis or through limited test performance studies (TPS). In addition, there is still a need to further harmonize and improve the validation framework and to adapt it to new technologies used in diagnostics.

The objectives of VALITEST

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

Validation data are not available for all the tests that are currently widely used in plant pest diagnostic laboratories.

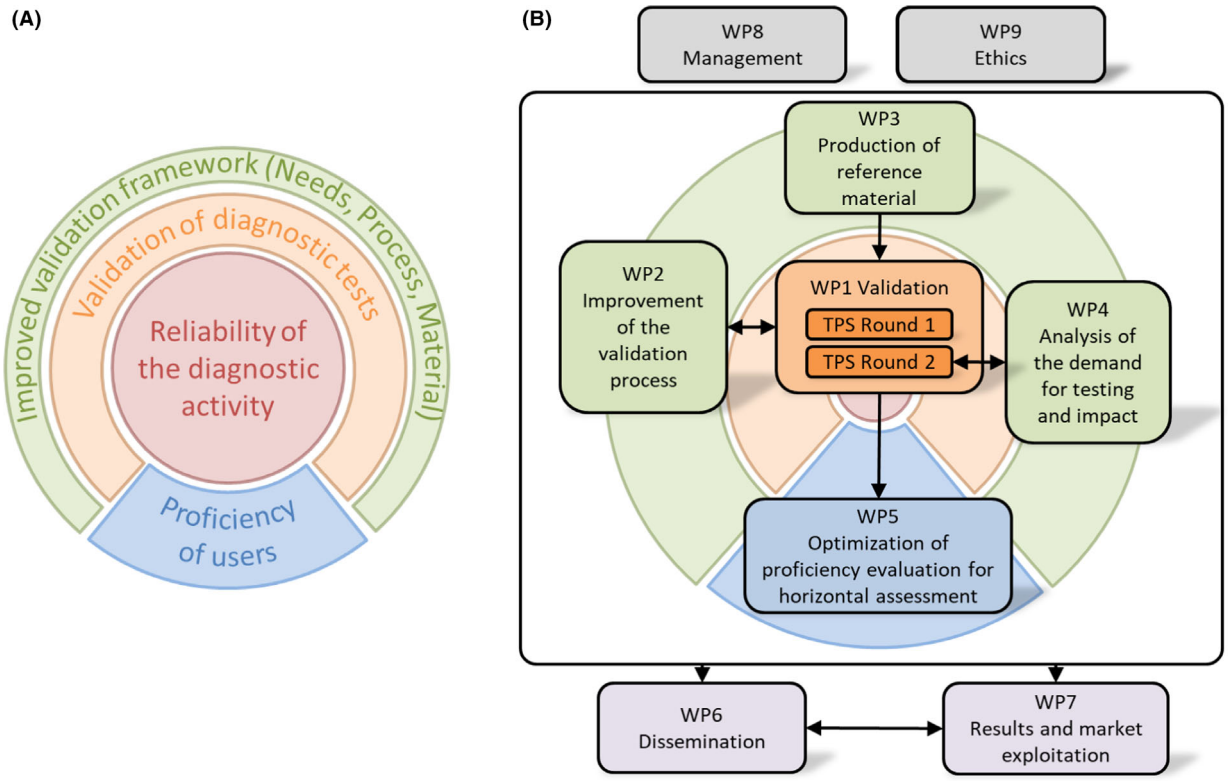

Fig. 1 Link between the objectives of the VALITEST project (A) and the description of the structure of the project (B). WP, work package. [Colour figure can be viewed at wileyonlinelibrary.com]

To guarantee the quality and validity of the results and to comply with the applicable regulations, additional validation is required. Thus, the first goal of VALITEST is to complement existing or produce new validation data for the detection and identification of plant pests that are of interest for various stakeholders in the region through the organization of two rounds of TPS.

Furthermore, based on the expertise of the partners and on the experience gained through the organization of several TPS, the project aims to improve the diagnostic procedures and the validation framework. Progressing further with this endeavour in the VALITEST project will enhance harmonization of controls and surveys in EU countries and beyond.

2. To stimulate, optimize and strengthen the interactions between stakeholders in plant health for better diagnostics

Despite the active role of EPPO at the regional scale and the existence of multiple channels and networks for collecting information about diagnostic tests and needs for development and validation, the mapping of such needs at the EU level is still incomplete and not up to date. VALITEST aims to fill this gap by collecting information from different stakeholders (e.g. researchers, diagnosticians, policy makers, inspection services, industries, seed companies, growers' associations, etc.) to build a comprehensive description of their needs.

Beyond the production of validation data for diagnostic tests for selected pests and the development of guidance documents for an improved validation process, the goal of the project is to serve forthcoming needs of different stakeholders at national and EU levels. For example, it will provide a basis for national reference laboratory (NRL) or European reference laboratory (EURL) activities in plant health, improve detection standards for all practitioners and produce data serving the need for mutual recognition, accreditation and certification of laboratories.

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

Currently, the diagnostic industry is not structured as an entity that can be solicited by other stakeholders. 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. Furthermore, setting up an appropriate structure for the EU plant health diagnostic industry will promote dialogue between the different stakeholders at EU level and beyond, and enhance the competitiveness of the plant health diagnostic industry.

The VALITEST consortium

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5. Loewe Biochemica GmbH, Germany
6. European and Mediterranean Plant Protection Organization (international organization)
7. Fera Science Limited, United Kingdom
8. National Institute of Biology, Slovenia
9. Gembloux Agro-Bio Tech – University of Liège, Belgium
10. Netherlands Food and Consumer Product Safety Authority, the Netherlands
11. ClearDetections B.V., the Netherlands
12. Stichting Wageningen Research, the Netherlands
13. International Plant Analysis and Diagnostics SRL (Ipadlab), Italy
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Activities and achievements so far (Fig 1B)

WP1: Validation of tests for identified priority pests

Main objectives

The main objective of WP1 is to produce validation data for tests where no or limited validation data is currently available. In 2019 and 2020, two independent rounds of TPS for prioritized pests in a range of matrices and for a range of diagnostic technology-related platforms (both laboratory and on-site-based) have been prepared and organized.

Description of the activities

Two rounds of TPS were organized. In 2019, the first round of TPS focused on six pests (see Table 1) selected before the start of the project based on the expertise within the consortium and on evidence of needs (i.e. co-funded EU surveys for 2017–2018). For the second round of TPS organized in 2020, the pests were selected in collaboration with WP4 to match the needs of stakeholders and the market (see Table 1). Organizers of round 2 were selected within the research consortium and through an online poll where each VALITEST consortium partner expressed their interest in organizing one or more of the six TPS.

In total the performance of 83 tests covering 11 pests and including about 10 000 samples were analysed during the two rounds of TPS (see Table 1; Ališ *et al.,* 2019a, Anthoine *et al.,* 2020). Between 11 and 34 participants

Table 1. Summary of the TPS organized in the framework of VALITEST

Pest	TPS organizer	Tests	Number of participants registered	Number of samples prepared
First round of TPS				
Erwinia amylovora	NIB	6 tests (real-time PCR, LFDs and LAMP)	32 (from 20 countries)	~900
Pantoea stewartii subsp. *stewartii*	NIB	6 tests (real-time PCR, PCR)	23 (from 16 countries)	~450
Citrus tristeza virus	ANSES	11 tests (ELISA, TPIA, Conventional RT-PCR, Real-time RT-PCR, RT-LAMP and ImmunoStrip)	17 (from 11 countries)	~1650
Bursaphelenchus xylophilus	ANSES	5 tests (conventional PCR, real-time PCR, LAMP)	21 (from 18 countries)	~430 DNA extracts ~280 spiked wood extracts
Plum pox virus	NVWA	8 tests selected (RT-PCR, real-time RT-PCR, DAS-ELISA)	17 (from 12 countries)	~700
Fusarium circinatum	FERA	6 tests (plating, PCR, real-time PCR)	20 (from 15 countries)	~640
Second round of TPS				
Tomato spotted wilt tospovirus	NIB	8 tests (DAS-ELISA, on-site tests, conventional and real-time RT-PCR)	21 (from 12 countries)	~1540
Xylophilus ampelinus	FERA	9 tests (ELISA, IF, conventional and real-time PCR)	12 (from 11 countries)	~570
Cryphonectria parasitica	UNITO	3 tests (conventional and real-time PCR)	11 (from 8 countries)	~220
Plum pox virus	ANSES	3 tests (LFD RPA, LFD)	15 (from 12 countries)	~640
Tomato brown rugose fruit virus	CREA	5 tests (conventional and real-time RT-PCR)	34 (from 18 countries)	~715
Xanthomonas citri pv. *citri*	ANSES	13 tests (conventional and real-time PCR, LAMP and direct molecular tests performed from Immunostrips or Whatman™ FTA cards)	19 (from 14 countries)	~960

ANSES, French Agency for Food, Environmental and Occupational Health & Safety (FR); CREA, Council for Agricultural Research and Economics (IT); FERA, Fera Science Limited (UK); NIB, National Institute of Biology (SI); NVWA, Netherland Food and Consumer Product Safety Authority (NL); UNITO: University of Turin (IT).
DAS-ELISA, double antibody sandwich ELISA; IF, immunofluorescence; LAMP, loop-mediated isothermal amplification; LFD, lateral flow device; PCR, polymerase chain reaction; RPA, recombinase polymerase amplification; TPI,: tissue print immunoassay.

from eight to 20 different countries were selected for each TPS (see Table 1). In total, laboratories from 31 countries participated in the TPS (Fig. 2).

Organization of the TPS included the selection of the pests and the TPS organizer, the selection of the tests to be validated and of the laboratories participating in the TPS, the preparation of the material, the dispatch of the samples, the completion of the TPS and the analysis of the results (Fig. 3). Few partners were involved in the organization of several TPS. Harmonization was ensured by using common criteria and rules for the selection of tests and laboratories (Alič *et al.,* 2019b), shared templates (TPS invitation letters, contracts, technical sheets etc.) and shared procedures defined when needed in conjunction with other work-packages. Note that the criteria for the selection of tests and participants as well as some TPS documents were modified in round 2 according to lessons learnt from round 1.

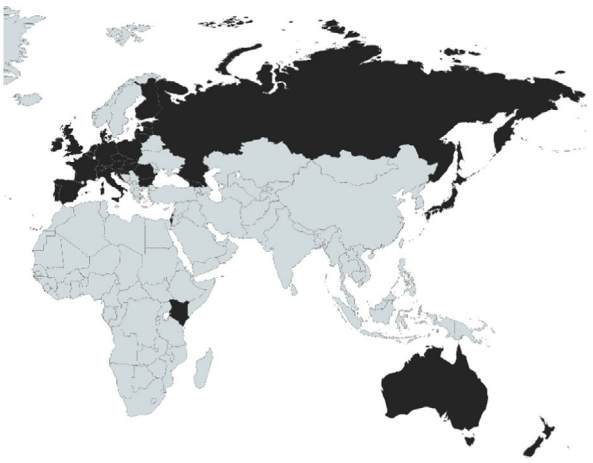

Fig. 2 Countries from which laboratories were selected to participate to at least one of the 12 TPS organized in the framework of VALITEST.

Preliminary conclusions

The organization of a TPS is a very complex and demanding process. Substantial knowledge was gained in round 1 and used to improve the workflow in round 2. The organization was shown to be easier if the timelines, rules and criteria which need to be followed are defined early on. It is worthwhile anticipating some possible scenarios and difficulties to enable a quick reaction in case of a problem and limit the impact on the course and organization of the TPS. Round 1 showed that possible delays (e.g. delays in obtaining the Letter of Authorization needed for quarantine pests and in obtaining chemicals/reagents) need to be taken into account. TPS organizers also learned that even though communication

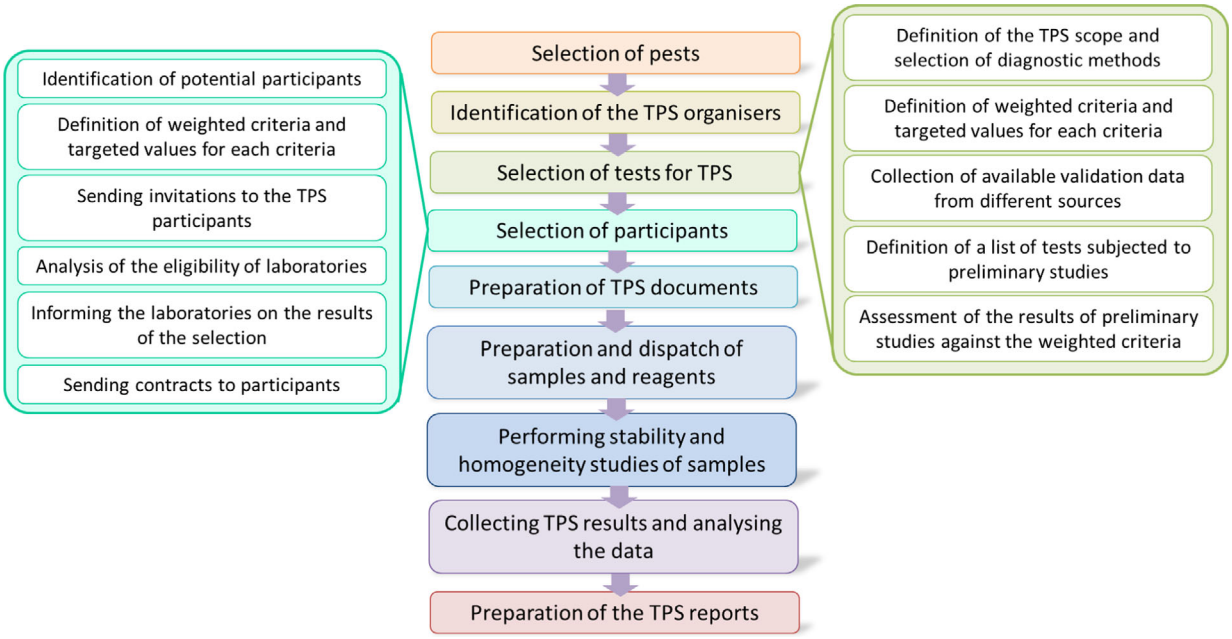

Fig. 3 Description of the workflow applied in the VALITEST project for the organization of a TPS. [Colour figure can be viewed at wileyonlinelibrary.com]

with TPS participants can be time-consuming, it is crucial to avoid misunderstandings and exclusion of some results.

Experiences from round 1 also highlighted the importance of ensuring a transparent process for the selection of the tests in particular towards commercial kit providers. Companies strongly recommend using their kits without any modification, but adaptations may be introduced by TPS organizers for various reasons. For example, the use of a harmonized protocol (e.g. common buffer and master mixes) can facilitate the TPS workflow and allow for more tests to be validated taking into account budgetary and time constraints. In the 2nd round of TPS, the companies granted permission to change some of the steps of the protocols when preliminary data showed that those changes led to results equivalent to the procedures recommended by the manufacturer.

Recommendations for the TPS organized in the VALITEST project are applicable to any TPS organization and could help reference laboratories such as the new EURLs. Moreover, other fields will benefit from the experience acquired from the project such as food microbiology, veterinary and human microbiology. The experience gained through VALITEST will be shared with the plant health diagnostic community through publications (book, EPPO Standards) and through training activities.

WP2: Improvement of the validation process

Main objectives

This work package aims:

(1) To improve the current EPPO Standards for validation of tests for plant pest diagnostics (PM 7/98, EPPO, 2019) and for the performance of interlaboratory comparisons (PM 7/122, EPPO, 2014) by incorporating new statistical tools to calculate and analyse performance characteristics and by providing recommendations for the design of test performance studies (e.g. number of samples, replicates and laboratories to be included to ensure an appropriate evaluation of the different performance criteria). These additional approaches will leverage the reliability of validation data and their value for decision making in risk management and routine diagnostics.

(2) To develop best practice guidelines for the selection, development, validation and routine use of high-throughput sequencing (HTS) in plant health diagnostic laboratories.

Description of the activities

The guidelines developed in the framework of this work package are based on a thorough literature review and are built in strong collaboration with different partners and experts including statisticians and diagnosticians.

Between December 2018 and June 2019, a first draft of recommendations for the revision of the EPPO Standards PM 7/98 (EPPO, 2019) and PM 7/122 (EPPO, 2014) for validation studies was prepared. The guidelines focus on an improved statistical analysis of several key parameters in the framework 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 an additional parameter in performance evaluation. Finally, it is suggested that the confidence interval for each statistical

estimate is determined. The proposed methodology is currently being applied to analyse the data obtained from the TPS organized by WP1 and the guideline will be adjusted accordingly.

Between December 2018 and June 2020, a first draft of the guidelines for the selection, development, validation and routine use of HTS in plant diagnostic laboratories was drafted chapter by chapter by a small group of experts from the VALITEST project. The guidelines provide recommendations to plant health diagnostic laboratories on the selection, development and optimization of HTS tests, on their validation and verification, and on their routine application in plant pest diagnostics, including the use of internal and external quality checks, and the interpretation and reporting of HTS test results. They are relevant for plant health diagnostic laboratories that intend to routinely use HTS technologies for the detection and identification of any plant pests (e.g. viroids, viruses, bacteria, fungi, protozoa, nematodes, arthropods, plants) from any types of matrix (e.g. soil, plant tissue, water, pure microbial culture) regardless of the type of HTS technology (e.g. shotgun sequencing, amplicon sequencing) and their application (e.g. surveillance programme, certification, crop protection). The guidelines were sent for review to a larger group of 36 experts from 18 countries in June 2020.

WP3: Quality assurance of reference material for validation purposes

Main objectives

The overall objective of WP3 is to establish and evaluate guidelines for quality assurance and standard operating procedures (SOPs) for the production of the different types of reference material used in validation studies for phytosanitary tests, including possible quantification of targets in reference material.

Description of the activities

First, a list of general minimum criteria for the production of reference material to be used in interlaboratory studies (including validations through TPS) was developed (Chappé *et al.,* 2019a). The list comprises criteria previously identified in international standards (ISO) and guidelines (EPPO), in deliverables of relevant projects (e.g. Q-Collect) and in other sources as well as additional criteria based on partners' own experiences. The identified criteria are the intended use of the material (e.g. TPS for detection methods for *Erwinia amylovora* in symptomatic plant material), its identity, traceability, commutability level (i.e. similarity to the actual sample), homogeneity, stability, assigned value (i.e. expected result of the test) and purity. Where relevant, each criterion was first defined as a series of levels from the highest to lowest, with the lowest ranking considered to be the minimum. Depending on the intended use, the reference material may need to fulfil higher levels of selected criteria and some criteria may not be relevant.

Then, a general SOP for the production of reference material for use in plant health diagnostics was developed (Chappé *et al.,* 2019b). The general SOP was designed based on (limited) information on existing SOPs and guidelines available to the consortium partners. The general SOP describes the different steps required in the production process, ranging from the different possible sources of the reference material (e.g. field material, working collection, reference material or certified reference material), tests to confirm its identity and 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 has to meet and their minimum required levels are incorporated.

Follow-up

The documents developed in this work package were used to prepare the reference material for the second round of TPS and will be used to draft an EPPO diagnostic Standard on the production of reference material.

WP4: Analysis of demand for testing and impacts

Main objectives

The two main objectives of this work package relate to a better understanding of the demands for current and future testing options. They are:

(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) To 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.

Elements of the multi-actor approach are incorporated by considering the demand for and benefits from the validation of existing tests, as well as requirements for future tests. In addition to the validation of the tests, this approach uses co-design methodologies with end users that can inform the design of tests and procedures and prioritization of targets, thus assisting faster market-readiness.

Description of the activities

The first task of WP4 consisted of identifying stakeholders' (e.g. diagnostic laboratories and NPPOs) testing priorities using surveys and setting up a general prioritization framework in collaboration with other work-packages. Using the framework, pests were ranked based on the results of the surveys whilst also taking supplementary information on each pest's status into account. Pests already covered by other research or for which tests were sufficiently validated were excluded. After adding additional high-priority pests, which are of interest due to their phytosanitary importance, WP1 partners volunteered for TPS organization for those pests.

The second task consisted of using a cost benefit approach (CBA) to assess the impact of the commercialization of tests for selected case studies.

WP5: Optimization of proficiency evaluation for a horizontal assessment

Main objectives

VALITEST aims to validate the diagnostic tests available for a selection of relevant plant pests. The goal of using validated tests is to ensure the quality of the results based on which control decisions will be taken. However, in the case of tests performed in laboratories, the targeted level of performance of a validated test is only ensured if it is performed by a laboratory regularly participating in proficiency tests (PT). In the field of plant health, this participation is not feasible for all the diagnostic tests on the market.

The initial objective of this work package was to 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.

Description of the activities

A range of data has been collected using three different approaches: (i) the study of accreditation scopes of some laboratories involved in diagnostics, (ii) a workshop with diagnostic experts and (iii) a survey sent to the laboratories listed in the EPPO database on diagnostic expertise. The data collected allow a better understanding of the expectations of laboratories, of what they would consider as acceptable and of the applicability of the horizontal proficiency testing approach (Rolland, 2019).

Based on these results, the acceptability of the approach has been discussed with representatives of national accreditation bodies. Based on these discussions, the views of experts collected previously do not constitute a sufficient level of evidence and the suitability of the approach should be demonstrated based on the analysis of proficiency testing results. Based on existing datasets, it was possible to draw some conclusions but not to demonstrate the suitability of the approach.

The most appropriate approach identified to limit the PT participation plan is to group the tests and evaluate the proficiency for these groups as described by the EA-4/18 guidance document (EA, 2010). However, the identification of the groups can only be done by the laboratory itself, taking into account its own parameters. As a follow-up to the work carried out within VALITEST, a plant health case study will be developed to accompany the guidance document and to show how plant health laboratories can use this approach to ensure the validity of results given.

WP6: Dissemination, communication and training

Main objectives

This work package aims:

(1) To 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) To disseminate the results of the project to a wide public, including researchers, policy makers and other stakeholders, via different meetings organized at EPPO and EU levels, webinars and through a project website.
(3) To ensure future harmonization of validation processes across the EU region by building capacities on validation processes.
(4) To build capacities of diagnostics laboratories to perform tests validated in the project by targeted training.

Description of the activities

The project website (https://www.valitest.eu) and twitter account (https://twitter.com/ValitestProject) were established and are regularly updated. In addition, a training and dissemination plan presenting the objectives of the training and dissemination activities and the tools provided to ensure that the objectives will be met was established.

The EPPO Database on Diagnostic expertise (https://dc.eppo.int) includes a specific section on validation data for diagnostic tests. Laboratories can deposit online validation data that they have generated on specific tests and these can be made visible to all users of the database. One of the objectives of VALITEST was to improve the searching capacity of the database to ensure optimal use. To evaluate the needs of users, a survey was organized. Further needs were identified during meetings with users. The new redesigned and more user-friendly database was launched in May 2020. Validation data obtained from the two rounds of TPS organized in the framework of VALITEST will be made available in the EPPO Database on Diagnostic expertise.

Online training activities (webinar series and practical sessions) on the concept of validation, on the organization of TPS and on the development, validation and routine use of HTS tests will be organized for diagnostics laboratories. Additionally, video tutorials will be prepared and made available on the project website.

Finally, in addition to the dissemination of the project results through scientific meetings and training workshops, lessons gained for TPS organization will be published in an open access book and TPS results in relevant scientific publications.

WP7: Market exploitation of the project results

Main objectives

One of the project's main aims is to swiftly bring onto the market tests validated according to international standards and produced by the Small and Medium-sized Enterprises (SMEs) manufacturing diagnostic kits.

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

In this activity, an EU Association of the Plant Health Diagnostic Industry (EPDIA) was established to ensure the

market sustainability of the SMEs by facilitating dialogue with stakeholders and decision makers. In parallel to the establishment of EPDIA, an EU Plant Health Diagnostics Charter describing the quality procedures for the production and the validation of commercial tests produced by EU manufacturers is being developed. This Charter will contribute to guarantee the quality and the reliability of the products to end users worldwide. Manufacturers' adhesion to EPDIA and to the Charter will permit SMEs to increase their competitiveness.

Description of the activities

The key exploitable results and exploitation routes have been identified for several work packages (WP1, WP5 and WP6). For these work packages, the results of the project could be used for further research activities, for creating and providing services, and in standardization activities. In addition, two general exploitation guidelines (one for industrial partners and one for research institution partners) have been developed to help partners reach the expected exploitation of the results.

To establish the EPDIA, benchmarking in other fields has been conducted and the information collected was used to better define the structure and the roles of EPDIA. In addition, a questionnaire on the establishment of the association has been prepared and sent to different stakeholders involved in plant health. As a part of this activity, the website of EPDIA is under development. It will contain technical information on the EU manufacturers' kits available on the market. This large database will allow end-users to easily and quickly check the availability of commercial tests based on the scope of the analysis they need to perform.

Finally, an EU Plant Health Diagnostics Charter for Industry is being established to improve EU SME competitiveness by defining guidelines for the quality and performance assessment of diagnostic kits before release on the market.

Further information

Further information can be obtained from the VALITEST website (https://www.valitest.eu) and twitter account (https://twitter.com/ValitestProject). In addition, the results of the project will be disseminated during training activities (including online webinars and online practical training sessions). Please contact us (contact@valitest.eu) for further information.

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VALITEST : Validation de tests de diagnostic pour favoriser la santé des plantes

VALITEST est un projet financé par l'UE qui vise à améliorer la fiabilité des tests de diagnostic effectués dans les laboratoires phytosanitaires de la région européenne et méditerranéenne. Ce projet est mené par un consortium de 16 partenaires composé d'instituts de recherche, d'entreprises privées (telles que les fournisseurs de kits), d'organisations nationales de protection des végétaux et d'une organisation intergouvernementale. Les procédures actuelles sur la validation des tests et sur l'organisation des essais interlaboratoires (en particulier l'évaluation de la performance des tests), harmonisées au niveau de la région, seront améliorées sur la base de l'expérience acquise dans le cadre de ce projet, en incluant des approches statistiques pertinentes, en adaptant le processus aux nouvelles technologies prometteuses (le séquençage à haut débit, par exemple) et en fournissant de nouvelles recommandation sur la production de matériaux de référence pour les études de validation. Ce projet fournira une description plus complète et plus précise des données de performance de 82 tests de diagnostic, ciblant 11 organismes nuisibles qui présentent un intérêt pour les parties prenantes de la région. Il répondra également au besoin de compétence des utilisateurs en développant une approche horizontale pour l'évaluation de la compétence des laboratoires et en organisant des activités de formation sur le concept de validation. Les résultats du projet stimuleront, optimiseront et renforceront les interactions entre les acteurs de la santé des végétaux, permettant ainsi de meilleurs diagnostics, et poseront les bases pour structurer la qualité et les offres commerciales des outils de diagnostic phytosanitaire, grâce à la création d'une association européenne de l'industrie du diagnostic phytosanitaire et d'une charte de qualité.

VALITEST: Валидация диагностических тестов в целях содействия карантину растений

VALITEST – проект, финансируемый ЕС, целью которого является повышение надёжности диагностических тестов, проводимых в карантинных лабораториях по всему европейскому и средиземноморскому региону. Проект осуществляется консорциумом из 16 партнёров, в состав которого входят исследовательские институты, частные компании (например, поставщики диагностических комплектов), национальные организации по карантину и защите растений и одна межправительственная организация

(ЕОКЗР). Нынешние согласованные процедуры валидации и организации исследований эффективности тестов будут усовершенствованы на основе опыта, полученного в ходе осуществления проекта путём включения статистических подходов, адаптации процесса к новым перспективным технологиям (например, высокопроизводительному секвенированию) и предоставления руководств по производству контрольных материалов для валидационных исследований. Проект предоставит более полное и точное описание работы 82 диагностических тестов для 11 вредных организмов, представляющих значение для заинтересованных сторон региона. Кроме того, он будет способствовать удовлетворению нужд квалифицированных пользователей путём разработки горизонтального подхода к оценке производительности лабораторий, а также путём организации учебных мероприятий по концепции валидации. Результаты проекта будут стимулировать, оптимизировать и укреплять взаимодействие между заинтересованными сторонами в области карантина растений для лучшей диагностики, а также заложат основу для структурирования качества и коммерческих предложений по инструментам карантинной диагностики благодаря созданиюспециализированной ассоциации и соглашения о качестве.

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