

## INTER-LABORATORY COMPARISONS

# How to do more with limited resources: the example of a shared quality management system for the organisation of inter-laboratory proficiency tests in the French Plant Health Laboratory

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### Abstract

As French National Reference Laboratory for the detection and identification of plant pests, the ANSES Plant Health Laboratory organises proficiency tests in order to ensure that laboratories certified by relevant authorities are capable of producing reliable analytical results.

Since 2014, the Plant Health Laboratory—which is composed of several separate technical units—has developed a centralised quality management system for organising proficiency tests within its different disciplines.

This paper presents the specificities of this management system based on in-house subcontracting and the strategy adopted by the Plant Health Laboratory to meet the requirements of ISO/IEC 17043.

### Keywords

- ★ Detection
- ★ Identification
- ★ ISO 17043
- ★ Laboratory proficiency testing
- ★ Plant pests
- ★ Quality management

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## Introduction

According to European regulation (EC) No. 882/2004 [EU, 2014], reference laboratories have to supervise and coordinate the activities conducted by certified laboratories (*i.e.* officially certified by a relevant authority) in order to ensure that they are capable of producing reliable analytical results. Proficiency testing (PT) is a way of checking laboratory testing performance by means of an inter-laboratory comparison. Non-compliant results in proficiency testing can have important consequences for the laboratory, such as the suspension or withdrawal of its official certification and/or its accreditation. It is therefore essential that the PT organiser be able to provide participants with a guarantee of its competence in organising proficiency tests.

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, has 11 reference and research laboratories, including the Plant Health Laboratory (PHL). The latter is the French National Reference Laboratory for the detection and identification of plant pests. In this context, it is involved in designing and organising inter-laboratory proficiency tests in which certified French laboratories are required to take part.

In 2013, the PHL's Unit for Tropical Pests and Diseases, based on Réunion Island, was accredited by French accreditation body COFRAC to organise plant health proficiency tests. This accreditation was formal recognition of its competence in organising proficiency tests and reliably assessing participants' proficiency.

This experience was the foundation on which a centralised quality management system was developed for all the PHL's units and disciplines. In this context, the proficiency testing service (PT service) was developed within the PHL to organise proficiency tests for detecting and identifying plant pests in accordance with the general requirements of standard ISO/IEC 17043 [2010], which is the normative reference for the organisation of inter-laboratory proficiency tests.



## Proficiency tests in the area of plant pests

The usual procedure for proficiency tests to detect and/or identify plant pests entails an organising laboratory (the organiser or provider) sending identical sets of samples to a group of participating laboratories (the participants) for the detection/identification of one (or more) target plant pest(s). The samples are intended to simulate the kind of samples that are routinely analysed. The participants are not informed of the expected results (assigned values), and are requested to perform the (blind) analyses just as for routine samples. To ensure that the inter-laboratory comparison is reliable, samples are validated by the organiser in terms of status (the assigned value results from the organiser's own experimentation and is consequently defined independently from the participants' results), homogeneity and stability. The results obtained from the samples are returned to the organiser to assess compliance with the expected results. A PT report containing the results of this performance assessment is drafted and sent to each participant.

Good results provide independent and objective evidence of effective analytical quality assurance [Stuart and Squirell, 2001], and encourage the laboratory to maintain this high level of performance. Conversely, poor results can help reveal anomalies in the analytical process. Subsequently, a causal analysis is conducted and an action plan implemented to improve the laboratory's performance.

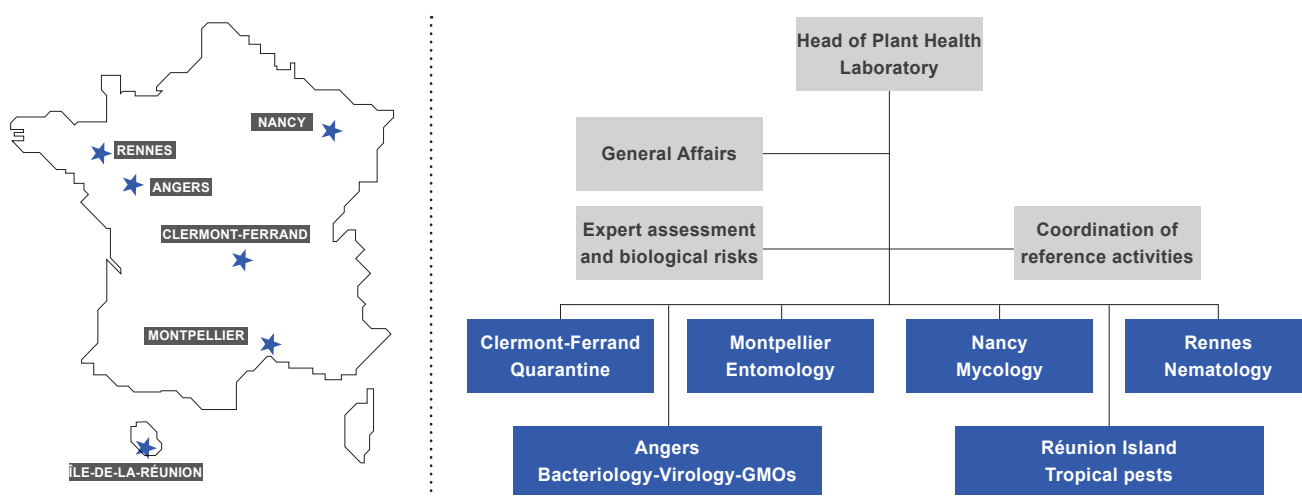
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## Organising plant health PT within ANSES

### ■ In-house subcontracting

The Plant Health Laboratory is composed of six specialised sites (Figure 1): Angers (bacteriology, virology and genetically-modified organisms), Clermont-Ferrand (virology and quarantine facilities), Montpellier (entomology), Nancy (mycology), Rennes (nematology) and Saint-Pierre on Réunion Island (tropical pathogens). The administrative headquarters are located in Angers, as are three cross-functional units which organise and coordinate the activities of the six specialised technical units.

**FIGURE 1/** Organisation of the Anses Plant Health Laboratory (with specialised technical units in blue).



The proficiency testing service, which is part of the cross-functional «coordination of reference activities» unit, is in charge of organising proficiency testing (PT) on behalf of the PHL. To do so, the PT service relies on the PHL's specialised technical units within the framework of an in-house subcontract (support agreement). This subcontract concerns the technical activities of preparing, validating, packaging, labelling, and shipping the samples. The PT service does not subcontract the planning of the proficiency test scheme, evaluation of performance or authorisation of the final report, as shown in figure 2.

The subcontracted work is covered by a support agreement between the PT service and each specialised technical unit, with general provisions applicable to all proficiency tests organised under the support agreement. The support agreement provides the overall framework. The specific provisions applicable to each proficiency test are described in the PT plan established prior to the proficiency test and signed by both the PT service and the specialised technical unit. The PT service remains responsible for the subcontracted work with respect to participants and other interested parties.

### ■ Organisation of the PT service

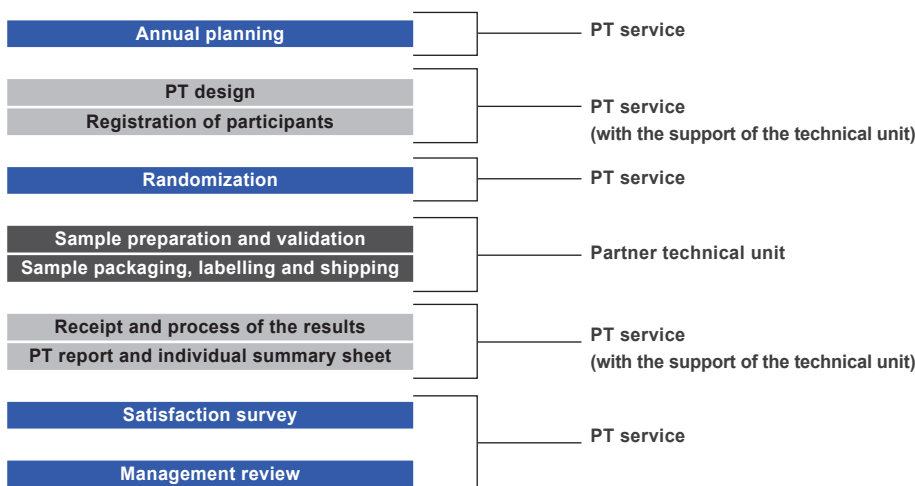
Organising proficiency tests involves different key functions within the PT service:

- the head of the PT service, responsible for its management in conjunction with the head of the PHL, authorises distribution of the PT reports;
- test coordinators. There is one coordinator per discipline or type of proficiency test: one coordinator for the nematology proficiency tests (working in the Rennes technical unit), two coordinators for the virology proficiency tests (one in the Angers unit and the other

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in Clermont-Ferrand, each with different areas of competence), one for the bacteriology proficiency tests (also working within the Angers unit), one for the mycology proficiency tests (working in the Nancy unit), one for the entomology proficiency tests (in the Montpellier unit) and finally one for the proficiency tests in tropical bacteria and viruses (in the Réunion island technical unit). The coordinators are the project leaders for the proficiency tests within their area of competence: they each have to coordinate the test design and oversee all work and activities relating to its implementation (whether technical operations, statistical analysis, etc.). They guarantee confidentiality and ensure communication with the participants. They also validate the PT report. Each test coordinator works within the technical unit specialising in the discipline concerned, thus facilitating supervision of the work carried out under the support agreement. However, the test coordinators work directly for the PT service and act under its authority.

**FIGURE 2 /** Roles of the PT service and the supporting technical unit for organising proficiency tests within the PHL.



As the number of coordinators is limited to one per discipline, for this function, the provisions for the appointment of a deputy coordinator require the contribution of a coordinator from a different unit. The deputy coordinator therefore operates remotely.

These provisions, by limiting the number of coordinators, are intended to optimise resources. Thus, the competencies required for this key function are monitored for a limited number of persons. Moreover, each coordinator performs coordination duties more regularly, as either the main or deputy coordinator, thus mastering the tasks in hand. The same proficiency test may be coordinated by the main coordinator, the deputy (who remains in his or her own specialised technical unit) or both together. The deputy coordinator can work remotely thanks to new communication technologies;

- the statistical analyst who helps implement all the statistical operations needed for the design, organisation and interpretation of the proficiency tests;
- the quality staff (quality manager and quality assistant) in charge of the PT service quality management. This includes ensuring that PT is always organised in accordance with the PT service's quality management system.

Organising proficiency tests also involves different key functions within the supporting tech-

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nical unit:

- the head of the technical unit, responsible for its management. The head commits the unit's resources in keeping with its supporting agreement with the PT service;
- the technical manager, responsible for technical operations (*i.e.* selecting appropriate samples then preparing, validating and packaging them);
- technical operators, who conduct the laboratory experiments under the responsibility of the technical manager;
- the operator responsible for labelling who labels the samples and prepares the packages of samples.

Figure 3 shows the PT service's organisation chart and the relations between these different stakeholders.

Although hosted in the PHL headquarters in Angers, the PT service operates on a multi-site basis from day to day. This is possible through information technology tools which foster cooperation through networking, the sharing of knowledge, pooling of information and remote communication/management in real time.

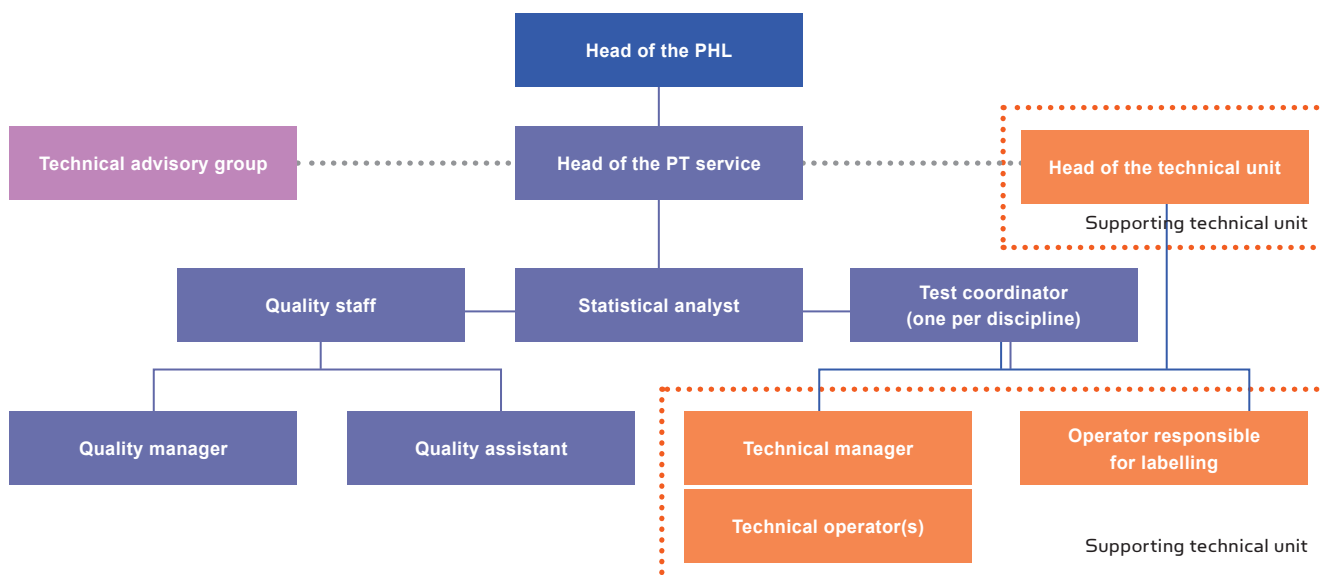
These tools include:

- a shared server designed so that different access rights can be attributed to different users;
- an electronic document management system for the PT service's quality documentation, including its accessibility and use for all users (including supporting technical units);
- computer applications for instant messaging and audio/video/web conferences with screen sharing (*e.g.* Lync);
- computer applications for the multi-site validation of documents while ensuring the security of PDF signatures (*e.g.* Foxit phantom).

## ■ Management system

Organising proficiency tests is a highly technical activity (Stuart and Squirell, 2001) which must be supported by a solid quality management system and technical skills. The accreditation according to ISO/IEC 17025 [2005] of each supporting technical unit in line with its

**FIGURE 3 /** Organisation chart of the PT service and relations between the key functions involved in proficiency test organisation.



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reference mandate, guarantees both, as ISO/IEC 17025 is the normative reference on the competence of testing laboratories.

The support agreement requires in particular that the technical unit be accredited for the analytical method used to validate the sample, *i.e.* determining the assigned value, and ensuring sample homogeneity and stability.

In addition, to meet the requirements specific to ISO/IEC 17043 [2010], the PT service manages the organisation of each proficiency test as a project based on the PDCA (Plan Do Check Act) continuous improvement model, as shown in figure 4.

When the PDCA approach is applied to each production cycle of a proficiency test, the production steps can be standardised and levers found so that there is continuous improvement from one cycle to the next (virtuous circle).

This improves the overall performance of the PT organisation process. Indeed, the configuration of the PT service, with a single centralised quality management system for several separate technical units, makes it possible to implement corrective/preventive actions cutting across all the disciplines involved. Consequently, it is more efficient in capitalising on information, anticipating risks and ensuring continuous improvement than if each technical unit had its own independent quality management system.

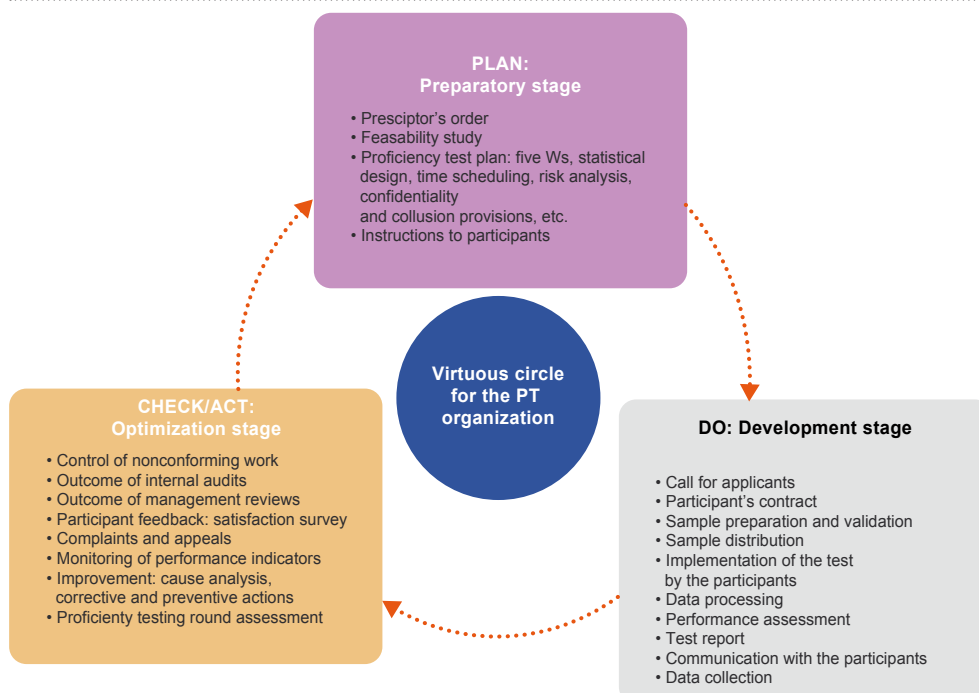
## Experience to date

Advantages of this centralised quality management system

There are several advantages to this mutual management system in organising PT. In accordance with ANSES policy objectives, the main advantages are explained hereafter:

- greater legibility for participants: a single documentary system, harmonised practices,

**FIGURE 4 /** Project management based on a PDCA model applied to the organisation of proficiency tests.



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single centralised management of non-compliances, customer feedback and continuous improvement;

- the rationalisation of resources and means: saving resources (a single quality management systems vs. six potential ones if each technical unit had its own), sharing of tools and information, dematerialisation of documents, and capitalising on the technical units' ISO/IEC 17025 quality management systems;
- better exploitation of information: pooling of non-compliances, generalisation of corrective/preventive actions to all disciplines;
- structural changes (e.g. normative change) are easier to integrate;
- greater flexibility and the possibility of a «variable geometry» configuration through in-house subcontracting, so as to offer proficiency tests tailored to the ever-changing phytosanitary context with appropriate responsiveness (possibility of including new technical fields, and resorting to external subcontracting). This is of crucial importance in guaranteeing the import/export of pest-free plant material.

### ■ Difficulties experienced in this approach

A major difficulty encountered when developing this centralised management system was to obtain the support of all the staff concerned by this project. The change of scale was a key issue to be clarified, so that the technical units did not have the impression that they were losing control. The management team's committed involvement was essential in overcoming these misgivings and creating a climate of confidence.

**TABLE 1/** Characteristics of the four PTs organised by the PT service in 2015, completed and with customer feedback.

Proficiency test (N°)	Field / technique	Target organism	Number of samples (in each participant panel)	Supporting technical unit	Number of participants	Results of the satisfaction surveys		
						Answer rate	Overall rate of satisfaction	Detailed rate of satisfaction (each question is considered)
FD/2015	Virology Real-Time PCR	Grapevine phytoplasmas	22	Angers	9	100%	100%	97%
15PPV	Virology ELISA	Plum Pox Virus	22	Clermont-Ferrand	11	64%	100%	100%
15XD	Bacteriology Conventional PCR and isolation	<i>Xanthomonas axonopodis</i> <i>pv. dieffenbachiae</i>	16	Réunion Island	7	71%	100%	98%
15BXE	Nematology Real-Time PCR	<i>Bursaphelenchus xylophilus</i>	15	Rennes	3	100%	100%	100%
<b>Total</b>					<b>30</b>	<b>81%</b>	<b>100%</b>	<b>98%</b>

More generally, the successful implementation of such a system requires the management team's involvement and rigorous management and monitoring on a daily basis.

### ■ Customer feedback

Once a proficiency test's report has been issued, participants are invited to take part in a satisfaction survey in the form of an online questionnaire. Clients are also given the opportunity to submit complaints during proficiency testing and, if they do not agree with the performance evaluation, to appeal within one month of the PT report being sent.

No complaints or appeals have been recorded for the four completed proficiency tests orga-

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nised by the PT service to date. As detailed in Table 1, the satisfaction surveys covered a total of 30 customers. The response rate is very high (81%). The overall rate of satisfaction is 100% and, in detail (if we consider each question), the rate of satisfaction is 98%. This organisation therefore appears to fully satisfy clients and meet their expectations.

A survey dedicated to the certified French laboratories and more specifically oriented towards this change in organisation will be conducted in mid-2016, when most of these laboratories will have already experienced this new organisation.

## Conclusion

The use of analysis methods capable of producing reliable analytical results is a prerequisite to the effective control of quarantine plant pests. Proficiency testing is considered to be one of the most reliable ways of verifying and coordinating laboratories' analytical proficiency.

Plant pest proficiency tests have a number of notable features including the processing of qualitative results [Chabirand *et al.*, 2014; EPPO, 2014]. Not only do laboratories have to demonstrate their ability to produce accurate analytical results, but proficiency test organisers also have to demonstrate their competence in organising proficiency tests within their area of expertise.

The development of this centralised quality management system provides a transition from individual experience to mutual knowledge in the field of PT organisation. This capitalisation of experience has proved valuable not only at the PHL but also more widely. Experts from PHL have notably helped prepare EPPO Standard PM 7/122 [EPPO, 2014].

The centralised quality management system developed by the PHL relies on the strong foundations of the ISO/IEC 17025-accredited systems of the different technical units. Its development was possible because the ISO/IEC 17025 and ISO/IEC 17043 standards share common structure and contents. According to recent exchanges with the French accreditation body, such a centralised quality management system could be accredited provided that there is a close fit between the ISO 17025 scope of accreditation for the technical units and the requested ISO 17043 scope of accreditation for the PHL.

The centralised quality management system developed by the PHL provides an example that could be applied in other fields to entities similarly composed of different "technical units" (e.g. food safety or animal health).

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