

# Validation and Verification of Australian Plant Health Diagnostic Protocols - Workshop Proceedings



OFFICE OF THE CHIEF PLANT PROTECTION OFFICER, DEPARTMENT OF  
AGRICULTURE, FORESTRY AND FISHERIES

Validation and Verification of Australian Plant Health Diagnostic Protocols - Workshop  
Proceedings

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**Australian Government**

**Department of Agriculture,  
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## EXECUTIVE SUMMARY

Development of effective National Diagnostic Protocols to identify Emergency Plant Pests (EPP's) is a critical step in managing the biosecurity threats to Australian agriculture and environment. Recognition of this fact has been the imperative behind the work of the Subcommittee for Plant Health Diagnostic Standards (SPHDS), which has developed a framework for the development and approval of diagnostic protocols.

A workshop was held in Adelaide on 24<sup>th</sup> September 2007, as part of the 16th Biennial Australasian Plant Pathology Society conference, to introduce the framework and discuss issues around the development of diagnostic protocols. Attended by 37 participants from Australia, New Zealand and South Africa, nine speakers presented on the work of SPHDS, development of diagnostic protocols in Australia and NZ and laboratory accreditation. The discussion that followed showed support for the work of SPHDS, but pointed to the level of difficulty in developing, validating and verifying diagnostic protocols. Of particular concern was the lack of continuing funding available for protocol development and the lack of recognition and support for development of diagnostic protocols by the relevant governments employing the plant health professionals with the skills to undertake this work. In addition, the development of new protocols and the validation/verification of existing protocols were impeded by the difficulty in obtaining positive controls for tests either from the inability to import these into Australia, or the inability to transfer them between states and institutions within Australia. There was also recognition that the processes involved in development and approval of diagnostic protocols take a significant amount of time and resources which most plant health professionals are unable to provide.

Five recommendations to address these issues have been made as a result of this workshop, and these will be presented to the relevant authorities through SPHDS and OCPPPO. It was concluded that if these issues are not addressed, the overall diagnostic capacity and capability for emergency plant pests is and will continue to be severely impacted upon.

Barbara Hall  
Workshop Coordinator



## INTRODUCTION

The Subcommittee on Plant Health Diagnostic Standards (SPHDS) developed a national framework for the development and approval of national emergency plant pest diagnostic protocols.

The workshop was held on 24 September 2007 at the 16th Biennial Australasian Plant Pathology Society Conference in Adelaide. It was designed for people who have developed or who intend to develop diagnostic protocols for the identification of emergency plant pests. The workshop provided an introduction to the requirements of developing a protocol and a demonstration of the methods used to validate and approve them as National Diagnostic Protocols. The opportunity was also taken to make general presentations on accreditation and to introduce aspects of the draft Field Application Document for the plant health accreditation scheme. The workshop was attended by 37 participants representing:

- Australian Quarantine Inspection Services
- Biosecurity New Zealand, Ministry of Agriculture and Forestry, New Zealand
- Crop and Food Research Australia Pty Ltd
- CSIRO Ensis
- CRC National Plant Biosecurity
- Department of Primary Industries, Victoria
- Department of Agriculture, Forestry and Fisheries
- Department of Primary Industries & Fisheries, Queensland
- Department of Primary Industries Forestry & Mines, Northern Territory
- Department of Agriculture and Food, Western Australia
- Enza Zaden Australia Pty Ltd
- Horticulture Research Limited
- Murdoch University
- National Association of Testing Authorities
- Plant Health Australia
- Private Consultant Brisbane
- Scholefield Robinson Horticultural Services Pty Ltd,
- South Australian Research & Development Institute Plant Research Centre
- Western Cape Department of Agriculture, South Africa.



The Office of the Chief Plant Protection Officer (OCPPO) and SPHDS will use the outcomes of the workshop to advance issues that affect the development, validation, verification and review of plant health diagnostic protocols, particularly those for emergency plant pests and diseases.

The workshop provided an opportunity for participants to voice impediments they had experienced in attempts to develop, validate, verify and review plant health diagnostic protocols.

## BACKGROUND - OCPPO AND SPHDS

OCPPO facilitates and contributes to the building and enhancement of Australia's national plant health diagnostic capacity. The Office coordinates and manages key national plant health diagnostic programs for emergency plant pests (EPPs) and works in partnership with Plant Health Australia (PHA), government, industry, Plant Health Committee (PHC), SPHDS, CSIRO, universities and Cooperative Research Centre for National Plant Biosecurity (CRC NPB) on plant health diagnostic programs and policy development. OCPPO has several programs one of which is the Diagnostic Program.

SPHDS was established in December 2004 as a subcommittee to the Plant Health Committee. OCPPO has an integral role in SPHDS with particular focus on the adoption and implementation of best practice and new standards to enhance Australia's capacity to rapidly detect of emergency plant pests, and to facilitate the development of the underlying capability required to respond quickly in the event of emergency pest incursions.

## ORAL PRESENTATIONS

### SPHDS AND REFERENCE STANDARDS FOR EMERGENCY PLANT PESTS

#### SPHDS and its Role

Dr Margaret William

*Dr Williams is the Manager of Diagnostic Services within the Department of Primary Industries and Water - Tasmania, Australia and is also the Chair of the Subcommittee on Plant Health Diagnostics (SPHDS).*

SPHDS was formed in December 2004 and reports to, the Plant Health Committee. The Subcommittee seeks to sustain and improve the health of plants and plant products and to assure biosecurity and market access through the application of best practice to plant health diagnostic laboratory services. In October 2005 a funding agreement was ratified by all state and territory governments, the Australian Government and 14 plant industry members. This agreement will assist in assuring timely and effective responses to emergency plants pests that could adversely impact on Australia's primary plant industries. SPHDS has been tasked to establish, implement and monitor professional and technical standards within plant health diagnostic laboratories through the development and maintenance of an accreditation system, and national diagnostic standards for emergency plant pests. The Subcommittee also participates in emergency plant pest preparedness and identifies diagnostic training needs. Membership of SPHDS includes representatives of universities, CSIRO, museums, industries (via PHA), government agencies and the New Zealand Ministry of Agriculture and Forestry which has observer status.

SPHDS achievements to date have been the: (1) endorsement of three reference standards that relate to the development and approval of diagnostic protocols for emergency plant pests, and (2) diagnostic training scholarship program. The Subcommittee is presently working with NATA to develop the Plant Health Program for the accreditation of plant health diagnostic laboratories. Once this document is approved by NATA it will become known as the Plant Health Supplementary Requirements for 17025.

The main challenges facing SPHDS in continuing its job of facilitating the development of diagnostic protocols are: (1) the sheer number of plant pests and diseases identified in the Deed and Industry Biosecurity Plans (2) the cost and funding of protocol development, validation and verification, and (3) AQIS import restriction of positive controls which are mandatory for protocol development, validation and verification.

#### Requirements for Diagnostic Protocols

Dr Jacek Plazinski

*Dr Plazinski is the Senior Scientific Advisors within the Department of Agriculture, Fisheries and Forestry - Canberra, Australia and is also the Co-ordinator of the Diagnostic Standards Working Group (DSWG) of the Subcommittee on Plant Health Diagnostics (SPHDS).*

The Subcommittee on Plant Health Diagnostic Standards (SPHDS) was assigned the task of developing a national framework for the development and approval of Australian plant pest diagnostic protocols. This has now been completed by the development and endorsement of the SPHDS Reference Standards No.2 and No.3. This presentation deals with SPHDS References Standards No.2: *Development of Diagnostic Protocols - Technical Procedures*. The purpose of this document is to provide guidelines and instructions to authors who wish to write and submit a diagnostic protocol to SPHDS for approval. Nationally endorsed protocols will be utilised by Australian plant health diagnostic laboratories for diagnosis of plant pests.

The RS No.2 is structured into three parts: Part A - providing procedures for the production of national diagnostic protocols; Part B - with instructions to authors of national diagnostic protocols; and Part C - describing procedures for peer review of diagnostic protocols by independent laboratory.

A diagnostic protocol should describe the methods used to identify diseases and their causal agents of specific plants. It must also provide guidelines to plant pathologists, field officers, consultants and even growers as to what shall be done and by whom, when a suspected pathogen/disease is found. Within a diagnostic protocol the following information should be included: symptoms, pathogen, host range, distribution, methods of isolation and storage, diagnostic test/s, pathogenicity tests, records, reference and national and/or international contacts. The diagnostic component of a protocol should include visual and background information, and comparisons with related species. For intermediate diagnosis and screening procedures the authors should describe collection and handling of suspect material, sampling methodology and time frames. For confirmatory procedures information of the diagnostic provider, reference material should be included. There are also other important issues that must be addressed by an author of diagnostic protocol. These issues are: sampling strategy, choice of detection methods, specimen handling, packaging and despatch of specimens, reporting on diagnostic results, communication, and consultation process.

Internationally, there are trends towards developing diagnostic protocols for plant pests and diseases. In the European Union there is a research program that addresses production and validation of diagnostic protocols for plant pests. The project, called DIAGPRO, is coordinated by the Central Scientific Laboratory (UK) and aims at producing over 50 protocols for exotic pests. Fifteen laboratories are involved in development of protocols and over 40 laboratories provide a ring-testing validation of diagnostic tests. The protocols are published as EPPO Diagnostic Protocols and can be downloaded from the EPPO web site ([www.eppo.org/Standards/diagnostic.html](http://www.eppo.org/Standards/diagnostic.html)).

The North American Plant Protection Organization (NAPPO) has only produced one diagnostic protocol for Karnal bunt, ryegrass bunt and rice bunt. In March 2006, The International Plant Protection Convention adopted a draft protocol for *Diagnostic Protocols for Regulated Pests* as an international standard - ISPM No.27. This IPPC standard describes procedures for official diagnosis of regulated pests relevant in international trade.

Part B of the SPHDS RS #2 provides detailed instructions to authors on national diagnostic protocols for emergency plant pests, and is based on the ISPM No.27. Therefore, any future diagnostic protocols developed in accordance with the SPHDS RS#2 should be in harmony with international standard ISPM No.27.

## SPHDS' Approval Process

Dr Therese Brackenbury

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*Dr Brackenbury is a Policy Officer within the Department of Agriculture, Fisheries and Forestry - Canberra, Australia and is also the Executive Office and Co-ordinator of the Diagnostic Strategy Group (DSG) for SPHDS.*

SPHDS Reference Standard No. 3 *Guidelines to the Approval Process of National Diagnostic Procedures and Protocol* is the second component of developing a national framework for development and approval of diagnostic protocols and follows on from RS #2. The approval process was developed around four possible scenarios in which an author could submit a protocol for approval by SPHDS. The first scenario covers the approval process for newly developed Australian emergency plant pest protocols. 'Scenario 2' deals with how an endorsed IPPC or other international diagnostic protocol will be approved as a Provisional National Diagnostic Protocol until such time as it can be validated in Australia. 'Scenario 3' sets out how a protocol submitted in an emergency response incident will be approved. And finally the fourth scenario is the review process for existing National Diagnostic Protocols which will be done automatically every three years to include

advances in diagnostic techniques and thereby creating the most optimal testing situation for the laboratories in terms of reliability, reproducibility, performance and hopefully costs.

Once a protocol has been submitted to SPHDS for approval, its two technical groups, the Technical Group and the Expert Panel will undertake the assessment process. The Technical Group will consist of SPHDS members and relevant professionals and they will determine: whether or not the protocol complies with RS #; verification has been undertaken by an independent laboratory; and that the Expert Panel has made a recommendation that the protocol be approved. The Expert Panel will be a group of plant health professionals selected by SPHDS to review an evaluation report submitted by an independent laboratory. In line with recommendation from these two technical groups SPHDS will approve the protocol and submit it for endorsement by the Plant Health Committee (PHC). Once endorsed the protocol will be recognised as a National Diagnostic Protocol and be utilised by plant health diagnostic laboratories in Australia for the diagnosis of that specific plant pest.

By providing this national framework SPHDS and its participants will be contributing to improving the diagnostic capacity, capability, accuracy and reliability of diagnosis, and response time which will overall widen our market access.



## EXPERIENCES IN PRODUCING, VALIDATING AND VERIFYING DIAGNOSTIC PROTOCOLS

### Developing a Diagnostic Protocol for an Emergency Plant Pest

Dr Brendon Rodoni

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*Dr Rodoni is a Senior Diagnostician within the Department of Primary Industries Victoria - Knoxfield, Australia.*

Dr Brendon Rodoni described his experiences in developing the Plum Pox Virus and Fireblight diagnostic protocols.

The Plum Pox Virus (PPV) protocol was developed in 1999 focusing on symptomatic diagnostics, epidemiology, ELISA and PCR. In its development great difficulties were experienced in maintaining a supply of positive controls as well as importing virulent strains of the virus to use as positive controls. Development of the protocol required a high demand on time and resources particularly when developing a high through put PCR system. A restrictive factor in developing the ELISA test in Australia was not having a valid control due to AQIS import restrictions. Consequently, validation had to be done in overseas to obtain reference samples which incurred further costs to the development of the protocol. Validation revealed that the two diagnostic tests had different sensitivities to the virus in different plant parts. It also highlighted the importance of authors being aware of sampling procedures in protocols particularly for emergency plant pest protocols. In 2000 this diagnostic test diagnosed PPV on an illegal plant import in to Australia. The author also studied background flora while sampling orchards for PPV and this greatly enhanced confidence in the diagnostic test.

The Fireblight protocol was developed in 1995 and in 1997 Australia experienced an incursion incident which uncovered a weakness in the protocol. The weakness was that the diagnostic test had not been validated overseas or in Australia during development. Only the acquisition of knowledge had been incorporated into the protocol. Neither had a survey been done of cross reactivity with background microflora which was later uncovered during a four-year surveillance-analysis program. Had validation taken place during development, these issues would have come to light before the protocol was used in an actual incursion incident. Validation of the protocol requires time and resources. Post-1997 an international and national collaboration effort resulted in the redrafting and verification of the Fireblight diagnostic protocol. The end result was a robust diagnostic test which repeatedly proved itself over a 6-year period. Robustness of the test greatly increases the confidence of the diagnostic test for diagnosticians.

Recently an international collaborative project was commissioned to evaluate PCR-based protocols for *Amylovora* strains that affect *Rubus* and some ornamentals, apples and pears. Collaboration with international specialists was considered an essential component in the protocol development to help address issues such susceptibility tests and availability of reference samples.

### Production of a Diagnostic Protocol for *Tilletia indica* (Karnal Bunt)

Ms Dominie Wright

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*Ms Wright is a Diagnostician within the Department of Agriculture and Food - Western Australia, Australia.*

Ms Dominie Wright described her experience in developing the *Tilletia indica* diagnostic protocol, this fungus is responsible for causing Karnal bunt in wheat.

The protocol was commissioned and completed in 2002 and 2003, respectively. It was developed in conjunction with NSW DPI. At the time the USDA had a protocol in place while CSL were developing one. The existing protocols were found to be similar, but different. Most of all they were confusing to read, extremely long and did not provided adequate diagnostic images of the spores.

Morphological descriptions were appropriate for a taxonomist, but not for a diagnostician. For diagnosis morphological descriptions need to be practical and easy to use. It was not possible to determine which one was more robust due to the BA/AQIS importation restrictions on positive controls. The only way the existing protocols were verified was by travelling overseas to obtain reference samples and training. This required the author to apply for additional funding. Proficiency in the diagnostic test was found to be critical for a successful diagnosis. The EU later produced their protocol which was found to be more readable.

Back in Australia the author drafted an Australian version using information mostly from the EU protocol as it had been ring-tested in six laboratories. Techniques were refined in the appropriately equipped laboratories, and the protocol was presented in a practical and easy to read format following the NATA guidelines for SOPs. On completion, the protocol was validated by various pathologists from different states utilising denatured spores. This Australian protocol has proven to be more robust than the international protocols as shown in the Pakistan incident in 2004.

The difficulties the author experienced in writing a diagnostic protocol included:

- the amount of time required to develop and write a protocol;
- the time and resources required for solving problems in methodologies;
- the unavailability of positive controls due to BA/AQIS import restrictions;
- poor recognition of the work author/s have undertaken to produce a protocol;
- poor communication; and
- inability to validate and verify diagnostic tests in Australia due to BA/AQIS import restriction of positive controls.

### Validation of a Diagnostic Protocol *Monilinia fructigena* - A Case Study

Mr Mark Braithwaite

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*Mr Braithwaite is a Diagnostician in the Plant Health and Environment Laboratory (PHEL) Investigation and Diagnostic Centre within MAF Biosecurity New Zealand.*

PHEL is involved in the diagnosis of plant pest and diseases in plant samples collected from surveillance programmes, public submissions, incursion responses, and interceptions at the border or within transitional facilities. The laboratory also provides technical advice on biosecurity issues (e.g. incursion responses and import/export requirements), as well as producing diagnostic protocols. PHEL is an ISO 17025 accredited laboratory with PC2 containment facilities. The development of a protocol requires the most up to date information on the pest biology and all potential identification techniques. Where little information is available, considerable amounts of time and resources are required to develop the techniques and test the protocols. The protocols need to be very clear and precise and written according to the SPHDS RS No.2.

The diagnostic protocol for *Monilinia fructigena* was developed independently in Australia and New Zealand, prior to the endorsement of the SPHDS Reference Standard No.2. There is an informal agreement between the two countries to share and jointly develop new diagnostic protocols. PHEL offered to coordinate the review and validation of the *M. fructigena* diagnostic protocol. Current methods of detection and identification were researched, and the two protocols were combined and formatted in accordance with the SPHDS RS No.2.

Prior to using a diagnostic protocol for the routine identification of an organism within a laboratory, it needs to undergo the process of validation or verification to ensure that it is fit for purpose. Validation is the process of determining whether a protocol or number of protocols effectively detect the target organism and includes procedure optimisation and demonstration of performance characteristics and evaluation of sensitivity and specificity. For *M. fructigena*, a range of published methods were tested under local laboratory conditions using multiple isolates/strains and internal controls. Where cultures were not available, imported DNA was used in molecular protocols for positive controls. The diagnostic tests were replicated to ensure consistency and repeatability. The

optimal protocol method is then written up into the SPHDS protocol format. In addition to this, as a requirement of PHEL's ISO 17025 accreditation, the optimised protocol is incorporated into our quality system, and includes quality control documentation (e.g. performance of strong and weak positive controls). Currently the *M. fructigena* diagnostic protocol has now been validated in New Zealand and is in the final stage of revision and formatting.

Verification, on the other hand, is taking a validated method and testing it in the local laboratory; this may involve some small modifications to the procedure to optimise the performance of the method in that laboratory. The process is less demanding than validation because the amount of quality control data required is significantly reduced.

For validation and verification it is essential to have access to reference material to study morphological features and test DNA extraction methods. Availability of positive controls also permits the optimisation of PCR reactions and avoids the possibility of false negative results.

Proficiency testing by key technical personnel is an integral part of ISO 17025 accreditation. PHEL currently has informal proficiency testing arrangements with plant pest diagnostic laboratories in New Zealand, Australia, and Canada. Proficiency testing of high impact exotic pest protocols is essential to ensure staff are able to conduct the procedures correctly to obtain the correct results.

Validation (or verification) of diagnostic protocols in New Zealand is aided by the fact the positive controls in the form of cultures can be imported and moved around the country. Landcare Research in New Zealand has an international collection of local and exotic cultures of fungi and bacteria. In addition, it has Environmental Risk Management Authority (ERMA) approval and MAF permit to import fungal and bacterial cultures into PC2 containment. MAFBNZ also has PC2 containment facilities and is permitted to transport cultures from the Landcare facility. Cultures such as *Xylella fastidiosa*, *Xanthomonas axonopodis* pv. *citri* and *Xanthomonas fragariae* cultures have been obtained in this manner permitting the extraction of DNA. MAFBNZ is also able to import extracted DNA for use as positive controls. No import permit is required for DNA. DNA of *Phytophthora ramorum*, *Liberibacter asiaticus* and *Liberibacter americanus* has been imported. PHEL is currently seeking its own approval to directly import exotic cultures of fungi and bacteria for the purpose of protocol development.



### Validation of Karnal Bunt

Mrs Barbara Hall (Team members - Jenny Davidson and Chris Wilmshurst)

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*Barbara Hall is Senior Research Scientist in the South Australian Research & Development Institute (SARDI), Adelaide, Australia*

Mrs Barbara Hall described her team's experience in attempting to validate the Karnal Bunt (*Tilletia indica*) protocol.

Karnal Bunt was the first diagnostic protocol in Australia to be submitted to SPHDS for approval and endorsement as a National Diagnostic Protocol. According to the SPHDS Reference Standard No.3 the protocol is required to be validated (verified) by an independent laboratory which in this case was SARDI. It was also SARDI's first involvement in the approval process. There are two different types of validations: The first is where the diagnostic test itself is validated by the author/developer to ensure that the test works. The second type of validation falls under the SPHDS terminology where an independent laboratory runs a submitted protocol, writes a report and identifies any gaps or errors that might exist. This process also ensures that any laboratory using the protocol for the first time can easily understand and follow the procedure to obtain a positive identification of the target pest.

In May 2007 SARDI agreed to validate two protocols, Karnal bunt and Fireblight, as this was initially considered an easy task, however, this proved not to be. The validation of Karnal Bunt was done by two diagnosticians experienced in *Tilletia* testings and wash test technique, and one inexperienced

diagnostician. There were a few issues in obtaining control samples such as staffing shortages, staff on leave, inadequate communication, and general coordination of the whole validation process. Blind samples (spiked with dead spores) were received, contained and tested (four weeks after receipt) following the protocol.

The initial validation of Karnal Bunt concluded that:

- That the procedure was clear to understand and easy to follow;
- The protocol required augmentation in descriptions of the spores as in its existing format it was open to interpretation especially by people inexperienced with the species.
- While conducting the test the microscope slides dried out very quickly when in use. The addition of moisture was not spelt out in the procedure. A contributory factor may have been due to pushing through all samples in one day.
- No *Tilletia* were found.
- The team verified that all procedures were carried out correctly and that the equipment was working properly.
- A possible error was identified relating to the quality assurance of the control samples.
- This is presently being reviewed for future validation.

The validation of Fireblight could not be undertaken as it was not possible to obtain the controls needed to run the tests.



## ACCREDITATION IN PLANT HEALTH LABORATORIES

### National Association of Testing Authorities

Mr Richard Makin

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*Richard Makin is the Manager of the Plant Health Program at NATA, Sydney, Australia*

NATA is a private non-for profit company and is Australia's Government-endorsed provider of accreditation for testing facilities, inspection bodies and producers of reference materials. Accreditation is defined as "Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks". Accreditation assesses technical competence and reviews management and technical aspects of quality systems (ISO/IEC 17025:2005). The benefits of being accredited include assurance of competency and maintenance of valuable collections, international recognition, promotion of trade, improvements in technology, staffing levels and reproducibility between laboratories. Plant health diagnostic laboratories will benefit through:

- recognition of staff knowledge and expertise,
- promotion of succession planning,
- the exchange of valuable knowledge,
- identifying areas of non-conformance and areas of improvement,
- implementing and assessing improvement processes,
- reproducibility,
- traceability of data,
- emphasis on training and education of staff, and
- efficiency and profitability.

In 2006 the Plant Health Field Application Document (FAD) to ISO/IEC 17025:2005 was first drafted. SPHDS and NATA are aiming to have a revised draft ready for public comment in December 2007 with the final version being issued in March 2008. Assessments to ISO/IEC 17025:2005 and FAD are planned from June 2008. Mr Makin also provided descriptions of how laboratories prepare for assessment.

### Experiences with NATA in a Diagnostic Laboratory

Dr Len Tesoriero

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*Len Tesoriero is a Diagnostic Plant Pathologist in the NSW Department of Primary Industries*

Dr Tesoriero presented his experiences with laboratory accreditation - the good and the bad.

His laboratory applied for accreditation for a broader spectrum of tests six years ago. This took 18 months, however, today with the availability of information the process should only take six months. Accreditation was found to be time consuming with one FTE putting together all the drafts of the SOPs and various other people along the way positioning us for accreditation.

The positive experiences with being accredited:

- Confidence in traceability of samples
- Competency of staff
- Verification of test methods
- Consistency and reliability
- Calibration of equipment etc
- Improved OH&S conditions.
- Implementing and assessing improvement processes (audits, documents reviews) although they may seem to get in the way of doing other work at the time. Audits expose problems or recommend ways to improve documentation.

- Preventative and correction actions provide us with documentation stating where things are going wrong and how these can be corrected. It provides us a process to follow these actions.
- Should there be litigation we now have documentation which will support our statements and actions in a diagnosis.
- Proficiency testing in the laboratory is still at an early stage. It has provided us with a system of self-testing.

The negatives with being accredited:

- Accreditation works well with a defined procedure/test which will provide a result. However, it cannot cater for general decision making process which is the real crux of diagnosis. Decision making in relation to suspect samples cannot easily be put to a hard document that is actually a procedure.
- Accreditation is costly - it increased the laboratory's cost by a third and requires a FTE who underpins the running the quality system.
- Compliance requires a sustained effort.
- Difficulties have been experienced by having a single signatory.
- Staff resistance.



## DISCUSSION SESSION

### OUTCOMES FROM DISCUSSION SESSION

Key findings are that:

- Australian and New Zealand plant health professionals support the free exchange of plant pest and disease diagnostic protocols between the laboratories of the two countries to prevent duplication and enhance building diagnostic capacity and capability;
- consideration needs to be given to the possibility that diagnostic protocols validated or verified in Australia or New Zealand could be adopted by the receiving country for immediate implementation;
- there is a need to establish the validation of processes (i.e. ring and proficiency testing) by utilising endemic pests;
- all government plant health agencies and industries should adopt the PHC-endorsed SPHDS Reference Standards;
- a project funded by the CRCNPB is investigating and addressing the packaging issues of plant-related biological samples;
- further discussion is required on the need of verifying a diagnostic protocol by an independent laboratory if the author has provided proof of extensive validation during development;
- the original author/s of the diagnostic protocol should be part of the review and update process;
- validation of a newly developed diagnostic protocol should also take place in country where the pest originated;
- the development of new Australian diagnostic protocols should be done in collaboration with overseas specialists;
- additional resources are required to enable the validation of newly developed diagnostic protocols against Australian background microflora;
- plant health diagnosticians in Australia support the SPHDS Reference Standards Nos 2 and 3 and that they are consider relevant to the standardisation and quality production of diagnostic protocols;
- an effective communication network is needed between the different federal, state and territory, and New Zealand diagnostic laboratories; and
- authors of diagnostic protocols should be notified of new decisions and processes being made with existing protocols - this can be facilitated through the communication network.

### RECOMMENDATIONS

The key recommendations are that:

- 1) Federal, states and territory governments, and industry should provide in-kind contribution in relation to funding, resources and additional time allocation to their diagnostic laboratories to support the development, validation, verification, proficiency testing, review and accreditation of diagnostic protocols. All or relevant aspects of this work should be factored in to the FTE's normal work program;
- 2) Federal, states and territory governments should fund and support the appointment of a FTE Test Coordinator who would be responsible for the verification and reviewing program of diagnostic protocols. A FTE is required due to high demands on time, work effort and resources

to execute this program. Responsibilities would included: establishing and maintaining communication network between the author, independent laboratory, SPHDS, AQIS and BA; obtaining and transporting control samples; organising permits; and establishing an overseas and national network as resources for reference material;

- 3) Biosecurity Australia (BA) and Australian Quarantine Inspection Service (AQIS) urgently need to address importation and national distribution restrictions of positive and negative controls of plant-related microbial isolates and strains. Current restrictions prevent the validation, verification, ring and proficiency testing of all existing and future plant health diagnostic protocols. Failure to permit importation and distribution of reference material will affect the robustness of the diagnostic protocol in identifying an emergency plant pest in an actual incursion incident;
- 4) BA and AQIS should urgently develop a single national procedure standard for import and movement permits of positive and negative control of plant-related micro-organisms for Australia and that this procedure is well communicated amongst all relevant plant health bodies and government agencies. New Zealand's system can provide a working model; and
- 5) Plant health employers should recognise and reward their diagnosticians and pathologists through the official publication of their protocols.

It was strongly emphasised by all participants that if no action is taken to address these recommendations, the overall diagnostic capacity and capability for emergency plant pests is and will continue to be severally impacted upon.



## WORKSHOP PARTICIPANTS

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LINKS TO SPHDS AND TENDRILS

<http://www.daff.gov.au/sphds>

[http://www.planthealthaustralia.com.au/corporate\\_documents/tendrils.asp](http://www.planthealthaustralia.com.au/corporate_documents/tendrils.asp)

