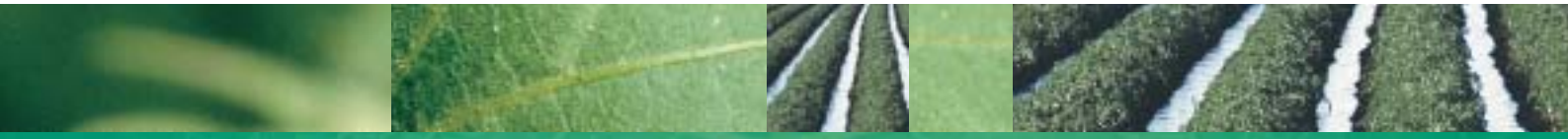
Developing a World Class
Plant Pathology Diagnostic Network
Workshop Proceedings

Plant Health
AUSTRALIA



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INTRODUCTION

In April 2002, the Chairman of Plant Health Australia (PHA) officially released the PHA commissioned report, *Assessment of the current status of the human resources involved in diagnostics for plant insect and disease pests* by Dr Jane Moran and Dr Ian Muirhead. Copies can be downloaded from the PHA web site (www.planthealthaustralia.com.au).

The authors made a series of recommendations regarding diagnostic capacity in Australia.

1) PHA should develop a strategic plan to establish a national network of diagnostic laboratories within a quality assurance (QA) framework.
2) The strategic plan should define the minimum resources required to maintain a national diagnostic capability.
3) A model for identifying and funding essential non-commercial activities of the diagnostic network (without the need for cost recovery) be developed.
4) The strategic plan includes procedures for succession planning and staff development, particularly for discipline areas that are considered to be at critically low levels.
5) The above recommendations be adopted as a two stage process:
   - secure enhanced networking and management of existing laboratories
   - identify centres with specific capabilities for biosecurity and secure their national roles and responsibilities.
6) A review of Australia's current and future requirements in taxonomic plant pathology and entomology be undertaken as a separate initiative.

The PHA Board considered the report and the recommendations above, and concluded that holding a sponsored workshop in conjunction with the 8th International Congress of Plant Pathology, would be the best approach for engaging international expertise, and for starting to address the majority of recommendations outlined above.

The workshop was held on 8 February 2003 to help determine the requirements critical in establishing an Australian diagnostic network, and to examine associated issues such as emerging diagnostic technologies, resource maximisation, and accreditation of diagnostic providers.

In Australia, as in many other countries, resources and budgets for diagnostics are limited. We must try to maximise and coordinate the resources that do exist, in order to ensure the ongoing effectiveness of our diagnostic services.

PHA will use the outcomes of the workshop to progress a diagnostic network that reduces duplication of effort and maximises available resources. In addition, a diagnostic network will provide opportunities:

- to create a critical mass of research expertise in plant diagnostics;
- to facilitate knowledge transfer for developed techniques; and
- for individual members of the network to more ably apply for research funding to address economically important pest and disease issues.

It is intended that the diagnostic network will be able to use peer reviewed diagnostic standards being developed by PHA. These standards, combined with a laboratory accreditation system and an accreditation system for individuals, will lead to the formation of a world class and internationally recognised diagnostic system.

The value of a diagnostic network is clearly enhanced if participating parties are accredited and test procedures standardised, meaning individual tests can be replicated in all the laboratories that have the appropriate technology.

In summary, this workshop provided an opportunity for participants to provide input into the development of a world class diagnostic system, which will enable Australian agricultural industries to be assured of reliable, and timely diagnostic test results.

BACKGROUND - PLANT HEALTH AUSTRALIA

PHA was established on 27 April 2000 as a public company limited by guarantee, and is a peak body responsible for coordinating the development of plant health policy in Australia.

The company provides a forum for plant industry and government to participate equally in developing beneficial approaches to key plant health issues, and manages agreed plant health programs on behalf of all members. PHA is working with its members to develop an internationally outstanding plant health management system that enhances Australia's plant health status and the sustainability and profitability of plant industries.

PHA members are:

Plant Industry

- Apple and Pear Australia
- Australian Banana Growers' Council
- Australian Citrus Growers
- Australian Cotton Growers' Research Association
- Australian Honey Bee Industry Council
- Australian Nut Industry Council
- Australian Vegetable and Potato Growers' Federation (AUSVEG)
- CANEGROWERS
- Grains Council of Australia
- Nursery and Garden Industry Australia
- Queensland Fruit and Vegetable Growers
- Ricegrowers Association of Australia
- Strawberries Australia
- Summerfruit Australia
- Winegrape Growers' Council of Australia
- Winemakers' Federation of Australia

Government

- Commonwealth Government
- Government of the Australian Capital Territory
- Government of New South Wales
- Government of the Northern Territory
- Government of Queensland
- Government of South Australia
- Government of Tasmania
- Government of Victoria
- Government of Western Australia

Associate members

- Australasian Plant Pathology Society
- Bureau of Sugar Experiment Stations
- Forest and Forest Products Committee

Note: the most up to date listing of PHA members is maintained at www.planthealthaustralia.com.au

REQUIREMENTS NECESSARY
FOR A WORLD CLASS DIAGNOSTIC NETWORK

Requirements for a world class diagnostic network

Dr Bill Roberts

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Introduction

Australia requires a diagnostic network that delivers services in a cost effective and timely manner across a full range of diagnostic needs.

Diagnostic services are currently delivered by a range of agencies including state/territory governments, the Commonwealth Government, commercial diagnostic laboratories, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), universities and Cooperative Research Centres (CRCs). Services are often provided on an ad-hoc basis with little coordination or national focus.

Australia needs to establish a comprehensive network of expertise (covering all significant pest groups) that operates in a cooperative manner across all agencies and across state borders. In building an effective operational network, challenging issues will have to be overcome, for example defining responsibilities, addressing the issue of lack of resources and the current lack of a national policy on plant diagnostics.

Why is diagnostics needed?

Diagnostic capacity is required to:

- support decision making in production agriculture;
- enable targeted pest control at internal and international borders;
- provide supporting evidence on a country's pest status;
- enable early detection of suspected exotic pests; and
- support the response action on exotic pests.

Optimal diagnostic outcomes

In an ideal world, we would have a diagnostic network that would:

- provide quick turnaround of results;
- have the capacity to deal with large number of samples;
- be cost effective;
- have comprehensive coverage of both exotic and endemic pests;
- provide an ability to detect low levels of target organisms;
- be extremely reliable (no false negative or false positive test results);
- provide access to a range of alternative technologies; and
- fit within an international agreement on diagnostic testing protocols.

Current diagnostic situation in Australia

Diagnostic services are delivered by a range of organisations (government agencies at the Commonwealth and state/territory level, CRCs, some universities and research bodies, and small private companies).

There is a general lack of national focus on diagnostic research needs, and often competition between laboratories for business.

For many exotic pest threats, no diagnostic capacity exists, and there are few accepted protocols for diagnostic testing, leading to differences in results for the same target pest.

Perhaps most significantly, there is no agreed funding mechanism for a national diagnostic system.

Examples where current system fails

Fireblight *(Erwinia amylovora)*

- Low bacterial numbers present making detection difficult
- Interfering organisms generating false positives

Potato Spindle Tuber Viroid

- Initial Polymerase Chain Reaction (PCR) test gave false positive
- Tomato crop destroyed before confirmation testing complete
- Need to balance risk of acting quickly on limited information against the risk of not acting quickly enough to enable eradication

Challenges for a diagnostic network

A significant challenge is complexity, with many thousands of pests of potential concern. However, grouping pests may simplify diagnostic needs, and new technology may improve reliability and capacity to test for large numbers of pests.

A diagnostic network must be flexible, and a key issue is maintaining general diagnostic skills - particularly in the field. There are some specialist areas where the number of diagnosticians is declining, and there is limited succession planning. We must develop a capacity to react quickly, and need to link into the expertise in overseas laboratories.

Funding must also be secured to conduct research, maintain skills and enable succession planning. Some means of equitable cost sharing across all agencies involved in diagnostics must also be put in place.

Finally, a network is likely to require some number of well resourced diagnostic facilities, but efforts should clearly be made to minimise duplication of costly infrastructure. Biological security is paramount, and must be considered when working with suspect exotic pests.

Issues to be addressed by a diagnostic network

Technology

Deoxyribose Nucleic Acid (DNA) diagnostics are very promising, but emerging technology needs to be validated by other established tests. Multiple technologies will continue to be needed for confirmation of test results, and the challenge of achieving accurate and timely results, will require the speed, costs and certainty of tests to be weighed up.

National policy issues

An examination of public and private good will most likely be required when examining appropriate industry and government roles and funding contributions.

Equitable cost sharing between states and between industries will be a key issue. The objectives of the network will also need to be refined (e.g. will the network focus on diagnostics for endemic pest management/production, exotic pest detection and/or border control?).

General network requirements

Participants need to be involved in a spirit of cooperation, not competition. While backup resources may be required, duplication of effort must be minimised or eliminated.

General diagnostic standards certainly need to be developed and endorsed, followed by development of agreed standards for specific pests.

Conclusions

Implementation of a national diagnostic network will most likely involve:

- developing a national policy framework in which a diagnostic network can operate;
- negotiating arrangements with international laboratories for collaboration;
- developing agreed diagnostic standards (national, regional or international);
- assisting with capacity building in centres of origin of the pests; and
- determining if a role exists for the International Plant Protection Convention.

US experience in developing a diagnostic network

Dr Laurene Levy

Dr Levy is a plant pathologist with the United States Department of Agriculture.

Introduction

In 2002, the US Congress allocated funds to agricultural-bioterrorism preparedness, including the establishment of a network of diagnostic laboratories for plant and animal pathogens. This funding was largely in response to an outbreak of Plum Pox Virus (PPV) in 1999 and the increasing threat of bioterrorism attacks since September 2001.

The purpose of this network is to function as a nationwide network of public agricultural institutions with a cohesive, distributed system to:

- quickly detect high consequence pests and biological pathogens that have been deliberately introduced into agricultural and natural ecosystems;
- identify such pests; and
- immediately report.

The following report discusses the experience of the United States (US) Department of Agriculture (USDA) in establishing a network of diagnostic laboratories within the USA, and how the network operates and is maintained.

Background

Since 1995, a number of plant pathogen pests have been introduced into the US; these include Citrus Canker, Karnal Bunt, PPV, and *Ralstonia solanacearum R3*. Such outbreaks, on average, cost approximately US$10m per year across the life of a program.

PPV symptoms were first noticed in the US by a grower in 1997-1998. In 1999, the grower took affected fruit to an industry meeting with farm advisers from several states. One adviser thought it looked like PPV, but then retracted this diagnosis, on the basis that PPV was not present in the US. Later that year, photos of the infected symptomatic fruit were sent to a number of people. Another scientist thought it looked like PPV, but again, was not certain. The photo was later e-mailed to an Animal and Plant Health Inspection Service (APHIS) scientist with ten years of experience with the pathogen, who was able to visually confirm PPV. One week later, APHIS and the Pennsylvania Department of Agriculture confirmed that it was in fact PPV and identified the strain.

The general failure of industry, state agencies, and extension services to rapidly identify the disease resulted in PPV remaining undetected in the US for three to four years.

A diagnostic network will help to minimise the chance of plant pests remaining undetected for long periods.

The US diagnostic network is made up of:

- farm advisers, county agents and extension plant pathologists;
- diagnostic clinics at some universities;
- State agriculture departments;
- Individual expert scientists at universities;
- industry (Agdia Inc. or Seed Testing Authority labs); and
- Federal scientists at USDA (APHIS and Agricultural Research Service).

There are numerous flaws in the system that contributed to the failure to detect PPV. Firstly, there was a low number of skilled farm or crop advisers/agents trained at the universities, and little money available for laboratories to improve diagnostic capabilities, or to train scientists in diagnostic methodologies. Many plant clinics associated with universities also have to be self sustaining, operating on a fee for service basis just to break even. State budgets are being cut and no money is available for equipment or reagents, and Federal quarantine programs often seek assistance from scientists in the states to collect and test samples for national surveys.

After the terrorist attacks in New York in September 2001, concerns were raised regarding crop and agricultural bioterrorism - the deliberate use of plant pests or pathogens as a weapon.

A key concern is to identify “unusual” plant pathogens, and to determine if emerging or re-emerging plant pathogens, chemically resistant pests, and pathogens with extended host ranges and new environmental tolerances are suspicious or not.

There was a real concern that there could be a completely new pathogen or bioterrorism event which the system could not cope with.

The new US Diagnostic Network - the National Plant Disease and Pest Diagnostic Network (NP2D2N)

US$43 million was allocated by Congress for agricultural-bioterrorism preparedness in 2002. Of that, $US20 million was earmarked to establish a network of diagnostic laboratories for plant and animal pathogens.

The US diagnostic network involves a steering committee and five key laboratories:

- UC Davis (Western Region);
- Kansas State (Great Plains Region);
- Michigan State (North Central Region);
- University of Florida (Southern Region); and
- Cornell University (North Eastern Region).

The overall goal is to enhance national agricultural security from bioterrorism attack through protection of health and productivity of plants in agricultural and natural ecosystems in the US.

The network will provide a functional nationwide network of public agricultural institutions with a cohesive, distributed system to quickly detect high consequence pests and biological pathogens that have been deliberately introduced into agricultural and natural ecosystems, identify them, and immediately report.

The network is specifically designed to serve the Federal regulatory agency (APHIS), state governments, Federal law enforcement, and Federal coordinating agencies such as Forestry and Department of Homeland Security (DHS). The network is implemented by universities, state laboratories, first detectors, and the National Agricultural Pest Information System (NAPIS).

Each of the regional centres is involved in:

- education and training;
- gathering data, information system development and maintenance;
- diagnosis and initial confirmation (including developing lists of experts and skills required for confirmation);
- notifying Federal authorities in an “event” diagnosis; and
- certification/qualification of laboratories.

Establishing the National Plant Disease and Pest Diagnostic Network

Data will be entered into NAPIS, which is maintained at Purdue University. Data will have to be transferred from local laboratories within a region to the regional laboratory who will forward it to NAPIS. There were early concerns regarding the range of unique systems in various regions.

In January 2003, the Southern Region ran a test with old data from eight systems. Once converted into xml (hypertext), all data went into NAPIS seamlessly. Through this system, some 28 states will soon be connected.

The network can be used to generate unique identification codes for sample identification (e.g. using region, state, county, and crop identifiers).

Each member of the network steering committee has a specific area of control. These areas are coordination, first detectors, data processes, diagnostic processes, data analysis, response activities and decision support, and funding.

Computers and servers have been (or are being) purchased to build the communications backbone of the network. Microscopes and digital imaging equipment is being purchased and molecular diagnostic equipment will be upgraded at some of the laboratories. The purchase of all equipment is being coordinated to standardise the equipment in regional laboratories.

Individual states are being encouraged to identify expert laboratories within each region. For example, expert states in the Western Region include California, Alaska, Hawaii, and Oregon. The expert laboratories will be fully functional with full diagnostic capabilities. Other states will perform triage on the ground and report any unusual findings to the relevant regional coordinator.

Best case scenario

It is hoped that the network will respond effectively and efficiently to bioterrorism events. Ideally the network will ensure:

- bioterrorism incidents are quickly identified and responders are notified;
- there is effective communication among all parties;
- pests are rapidly detected and diagnosis undertaken;
- pests are rapidly eradicated;
- national diagnostic centres are recognised and used (self-reinforcing);
- all efforts are united;
- public awareness increases; and
- increased national capacity for plant diagnostics (both related and unrelated to bioterrorism).

Worst case scenario

The worst case scenario could result in:

- lack of real network;
- logistical nightmare (laboratories are overwhelmed with samples);
- US agriculture compromised;
- pest misidentification;
- undetected attack on food security;
- network/computer system breakdowns;
- data classified or too sensitive to be widely shared; and
- no future funding.

National Plant Disease and Pest Diagnostic Network - APHIS involvement

APHIS is involved with the diagnostic network steering committee and is also a customer of the network. APHIS has accredited laboratories at Pioneer Seeds, and at Iowa State. APHIS is also increasing its staff and the support of the Center for Plant Health Science and Technology plant pathology laboratory. The National Inspection Service (NIS) is hiring four more plant pathologists for identification.

APHIS is a NP2D2N responder on a national level. The diagnostic network will improve the ability of APHIS to conduct national survey programs in states, regions, or across the US.

Technology application to survey and detection

Sensitive technology is needed to detect pathogens that are in low concentration and unevenly distributed. Technology must be sensitive, rapid, reliable, and user friendly.

PCR, RT-PCR, IC-RT-PCR, PCR-ELISA, and TaqMan chemistry for PCR is more sensitive than most enzyme-linked immunosorbent assay (ELISA) protocols, but whether it is more reliable is questionable.

ELISA protocols are easier, cheaper, and prone to less operator error and tolerant to some low level contamination. In some cases, a good monoclonal is extremely sensitive and specific.

In reality, citrus canker is identified visually in the field by inspectors with bachelor degrees or less. Confirmations are done in a laboratory by state regulatory scientists using inoculations to plants and PCR. PPV is identified in the states surveying by ELISA and then sent to a Federal laboratory for ELISA, IC-PCR, and PCR strain-typing assays. Potato mop top virus, a new problem, will be identified by state and federal scientists by its characteristic visual symptoms and ELISA. In this case, PCR is not too reliable.

The detection of pathogens is moving to mobile systems that can be used to rapidly conduct diagnoses at the farm gate. The US has decided to use the R.A.P.I.D. system by Idaho Technologies because of its rugged format and design. We have developed a test for citrus canker, which using simple sample preparations, can be conducted entirely in a mobile laboratory.

Advances in serological detection from military laboratories have resulted in electronic biosensor devices like Raptor. Preparation and detection can be achieved within 15 minutes, and the cartridges are reusable and are stable for one year.

Conclusions

Pathogens generally have a threshold, which once reached, causes infection. Several pathogens are present in nature at sub-clinical levels. Pathogens can become non-viable, yet through highly sensitive assays, they are detected. This raises the question of how regulatory agencies, first responders, and the new DHS use this information.

When considering all the technological options for detecting pathogens, the most important consideration is to find and use technology that is the most appropriate for the job that needs to be done.

THE ROLE OF EMERGING TECHNOLOGIES
VERSUS TRADITIONAL TECHNIQUES IN AN
EXOTIC PLANT PATHOGEN DIAGNOSTIC NETWORK

Experience with modern diagnostic techniques in diagnosing exotic pathogens

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Requirements of a plant disease diagnostic test

The basic requirements of any plant disease diagnostic test are detection and definitive identification of the causal agent. For a diagnostic test to be accurate and reliable, it must incorporate substantial levels of specificity and sensitivity, where 'specificity' is the capability to target the organism of interest in the absence of false positives (when it is not present) or false negatives (when it is present) and 'sensitivity' relates to the lowest number of pathogen cells per sample that can be reliably detected. Ideally, a diagnostic test must also be robust, simple to use and inexpensive. In addition to these basic requirements, a diagnostic test for an exotic or quarantinable pathogen must provide rapid and definitive confirmation of the presence or absence of the pathogen.

A rapid and definitive diagnosis is critical for effective incursion management and potential eradication of the disease.

"Know your enemy"

In Australia, the main concern to plant pathologists in identifying exotic diseases is the lack of familiarity with the disease and the causal agent. Most Australian scientists have never seen most of the exotic organisms that they are likely to encounter, and hence have no experience with the culturing or identification of the organism. The usual course of action when an exotic threat arrives on our shores is to try and locate the relevant national experts, search the literature and the internet for information, and then contact the relevant overseas experts for advice and diagnostic protocols. Depending on the available expertise and assistance, this course of action may take anything from several weeks to many months. Even when diagnostic protocols are available from overseas, the available tests may not be specific for the strain/s of the organism encountered in Australia or there may be unknown cross-specificity with Australian microflora and it is unlikely that tests developed overseas have been validated under Australian conditions. Alternatively, there may be a number of diagnostic tests available for a particular pathogen, so how do you decide which test to use?

Another concern is the difficulty of determining and prioritising potential exotic disease threats. Our understanding of the potential threats remains limited, despite the best monitoring and surveillance efforts and pest risk analyses. Even with dedicated surveillance programs such as the Northern Australian Quarantine Strategy coordinating routine plant disease surveys of Northern Australia and neighbouring countries, it is near impossible to identify all potential disease threats in such a remote and vast area. In an ideal world with unlimited resources, it would be prudent to source or develop, evaluate and validate diagnostic tests for potential disease threats prior to an incursion. Notwithstanding the limited availability of diagnostics expertise and financial resources, the sheer number of exotic threats of concern to Australia dictates that only a certain level of preparedness can be achieved.

What diagnostic techniques are available?

The techniques most often used for plant disease diagnostics include:

- examination of symptoms;
- isolation and culturing;
- morphology;
- microscopy;
- pathogenicity testing;
- serology;
- micro-arrays;
- PCR; and
- real-time PCR.

The simplest method of diagnosing a plant disease is by visual assessment of symptoms; however, this relies on the availability of an expert plant pathologist with experience with the disease symptoms and a sample with characteristic symptoms. Isolation and culturing of a pathogen may take days or even weeks, and the subsequent morphological identification of the pathogen also relies on the availability of relevant expertise. Pathogenicity testing to identify the cause of a disease is also time consuming, and is usually restricted to endemic isolates.

When comparing the relative advantages and disadvantages of diagnostic techniques, it is easy to get lost in the debate of 'traditional' vs. 'molecular' techniques - regardless of the test format, each individual diagnostic test should be evaluated for the key criteria of simplicity, robustness, specificity, sensitivity and speed. For an accurate and reliable diagnosis, use the technique that works and ideally, more than one technique should be used to confirm the diagnosis.

The application of emerging technologies

DNA-based diagnostic techniques are ideally suited to plant disease diagnosis, particularly exotic disease outbreaks, where the speed and accuracy of the diagnosis is paramount. By their very nature, DNA-based diagnostic tests that use PCR offer unparalleled specificity and sensitivity compared with most conventional diagnostic techniques based on isolation of the pathogen. PCR allows the detection of only a few propagules, and can also be applied to symptomless plants and a variety of plant samples (leaves, stems, roots or seeds). DNA-based tests also enable more precise identification (e.g. to the taxonomic level of 'strain'), which is not possible using conventional methods. Another advantage is that the format of PCR tests can be designed so that tests are robust, simple and user-friendly. This means that with proper training, the DNA-based diagnostic tests can be easily transferred to where the expertise is required.

There are a number of key considerations in relation to the application of emerging technologies to plant disease diagnostics.

Resources

- cost of each diagnostic test per sample
- equipment and facilities required to perform the test
- staff required to perform the test

Delivery

- number of tests
- throughput efficiency
- via a central or regional laboratory?

Expertise

- availability of expertise
- maintenance of skill levels, particularly for low use exotics

Sampling

- diagnosis depends on the type of specimen available
- sample preservation before and after diagnosis
- sample must be statistically representative
- correct sampling strategies are critical

Validation

- tests must be shown to be robust and repeatable for each application
- tests must be validated under Australian conditions

Quality assurance

- standard diagnostic protocols are required
- internal controls
- accredited laboratories
- expertise in more than one laboratory

Databases and reference collections

- availability of preserved specimens, culture collections, DNA and taxonomists
- collections should be representative and comprehensive
- import restrictions on cultures can sometimes be problematic
- is sequence information from Genbank trustworthy?
- information on Genbank is estimated to represent only one per cent of microbial diversity

When considering the application of a plant disease diagnostic test, the suitability of each test should be evaluated against the above-listed criteria. In the future, as more DNA-based diagnostic tests become available, it may be possible to generate multi-pathogen assays, which are either host-based (e.g. identify all important diseases of banana) or species-based (e.g. are capable of identifying all species of *Phytophthora*).

Conclusions

A plant disease diagnostic test must be specific, sensitive, robust, rapid and definitive. For a diagnostic test to be accurate and reliable the specificity and sensitivity of the test must be rigorously evaluated and the test must be validated for each specific application under Australian conditions.

The development and application of a plant disease diagnostic test must have a sound scientific basis. Information on the biology of the pathogen, disease transmission and epidemiology is necessary for an effective incursion response and to determine the feasibility of eradication. Following the diagnosis and confirmation of a disease outbreak, the subsequent containment and control of the disease and potential eradication requires an expert plant pathologist with knowledge of the appropriate disease management strategies.

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Emerging technology and its role in plant disease diagnosis

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Dr Elphinstone and Dr Barker work for the Central Science Laboratory (United Kingdom).

Introduction

This paper deals with newly emerging techniques being developed around the world (e.g. micro arrays and field PCR tests). The United Kingdom's (UK) Central Science Laboratory (CSL) is at the forefront of new technology development and in developing practical applications of diagnostic technology. A key consideration is how a modern diagnostic network would operate by taking advantage of these emerging technologies.

Background

CSL Plant Health Group maintains a central diagnostic facility for England and Wales (covering both plant pests and pathogens), and has more than 40 permanent diagnostic staff, backed by additional research and development staff.

Capital facilities are shared with the Food Safety Group and GM Inspectorate, and close linkages are in place with areas such as Plant Health Consultancy, Policy and Inspection services.

Diagnostic scenarios and technology

In general, diagnostic technology is driven by two differing strategies;

- sending samples to an offsite central laboratory or laboratories; or
- performing on-site testing.

Technology is also influenced by the balance between samples and target pests/pathogens. Generally there is a need to either process large numbers of samples with a small number of known targets (e.g. surveys) or to identify a potentially large range of targets with a small number of samples (e.g. diagnosis).

CSL has been developing technology that allows high throughput processing of large numbers of samples, as well as developing more mobile technologies for use in the field.

High throughput lab testing

One system developed by CSL is a real time PCR system using TaqMan® chemistry, which is ideally suited to high throughput detection

TaqMan® links two technologies together, employing fluorescent detection in conjunction with PCR (using a sensitive specific DNA amplification technique).

CSL has developed a high throughput, 384 well TaqMan® facility, which provides internal controls for every sample, a sample tracking and reporting system, and capacity to perform 12,000 PCR tests per week. All elements are linked using an 'in house' laboratory information management system.

Some CSL TaqMan® assays in use are:

- Potato mop top virus/Tobacco rattle virus multiplex in tubers;
- Tomato spotted wilt virus in individual thrips vectors;
- Tomato yellow leaf curl virus in imported individual whiteflies;
- Potato Virus Y (PPY), Potato Virus X (PVX) Potato Leaf Roll Virus in dormant tubers;
- Eyespot quantitation in cereals;
- Fusarium inoculum quantitation in potato seed;
- Potato brown rot detection in sewage effluent; and
- Potato ring-rot detection in potato seed.

A key advantages of real-time PCR is the capacity to undertake high throughput testing at a relatively low cost (approx £8 per sample including extraction and labour). Real-time PCR also provides for sensitivity/specificity, difficult matrices, provision of internal controls, and quantitation. All tests are closed tube, minimising the potential for contamination.

On-site testing technology

While the central laboratory scenario works well in some cases, the ability to conduct in field tests is becoming increasingly important.

The CSL Pocket Diagnostic™ technology is a genuine field based diagnostic kit.

CSL currently has 13 Pocket Diagnostic™ kits, including 10 viral kits, two bacterial kits and one fungal kit, specifically:

- Potato virus kits for PVY, PVX, Potato Virus A, Potato Virus S, and Potato Virus V;
- Other plant virus test kits for Pepino Mosaic Virus, Tomato Mosaic Virus, PPV, Tomato Spotted Wilt Virus and Impatiens Necrotic Spot Virus;
- Bacterial Plant Pathogen Kits for *Ralstonia solanacearum* and *Xanthomonas hortorum pv pelargonii*; and
- Fungal kit for *Botrytis cinerea*.

Some 4000 of these kits were used by CSL's Plant Health Inspection Service in 2002.

Decentralised technology

CSL is currently working with the Department for Environment, Food and Rural Affairs (DEFRA) Plant Health Division to develop rapid and portable real time PCR machines. These are being designed with biowarfare/bioterrorism implications in mind.

Using rapid and generic technology, the goal is to provide results within 20 to 40 minutes, using TaqMan, Nucleic Acid Sequence Based Amplification or SYBR® Green Assays without modification, and enable results to be transmitted via the internet.

Other emerging technologies

There are a number of highly parallel methods that have potential in the area of plant diagnostics, including:

- micro-arrays;
  - PCR arrays
  - oligo-arrays
  - pre-amplification of target
- Matrix Assisted Laser Desorption Ionisation Time-Of-Flight Mass Spectrometry (MALDI-TOF-MS); and
- direct sequencing.

Micro-arrays have the potential to be used to identify a large number of targets (up to 30,000 targets at once), but only on small sample numbers, and specificity/sensitivity is an issue.

A joint DEFRA/European Union (EU) project (DIAG CHIP) being coordinated by CSL involves the development of a micro-array of all EU quarantine potato pathogens, which includes testing for:

- 12 viruses;
- two bacteria;
- one fungus;
- six invertebrates (nematodes);
- one virus; and
- one phytoplasma.

The future of micro-array technology

As technology evolves, it may be possible to eventually develop a single test for all key plant pathogens and pests. This would be an ambitious task. While the EU Plant Health Directive lists 256 organisms, this is only the tip of the iceberg. Based on rough estimates, the challenge would be to develop a diagnostic capacity to identity:

- 42 viroids;
- 600-800 viruses;
- an unknown number of phytoplasmas;
- 400 bacteria;
- 2,500 fungi;
- 4,832 nematodes;
- 5,000 mites; and
- 50,000 insects.

Conclusions

Direct sequencing is gradually becoming cheaper and easier to use, and may evolve into a future diagnostic technique. As diagnostic techniques evolve, the lack of automated nucleic acid extraction systems (a current bottleneck) is likely to be addressed.

Generic platforms and technology will become increasingly important, and with the threat of bioterrorism, we are seeing a continued drive to move diagnostic testing into the field, and to enhance decision making.

Molecular technologies are starting to break down traditional discipline boundaries, and bio-informatics is becoming more important.

The key challenge is to ensure diagnostic technology is appropriate for particular scenarios, and ultimately provides for reliable results that are produced as rapidly as possible, and in a way that enhances decision making and responses to plant pathogens and pests.

OPTIMISING RESOURCE USAGE IN SETTING UP AND MAINTAINING A NATIONAL DIAGNOSTIC NETWORK

The US National Seed Health System: a diagnostic network model

Professor Denis McGee

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The National Seed Health System (NSHS) is a seed health diagnostic network in the US, of which elements may be useful as a model for diagnostic systems. The NSHS was developed in the 1990s to address the adverse effects of new phytosanitary regulations on trading and exchange of seeds in the international markets and to standardise seed health methods in seed industry quality assurance programs. The system resulted from a collaborative effort of industry, federal and state governments, and universities. It began operation under the overall supervision of USDA-APHIS in August 2001. The NSHS has three functions:

1. Accreditation of non-government agencies to carry out the processes of seed heath tests, field inspections, seed sampling, and visual inspections of seeds that are necessary to obtain federal phytosanitary certificates.
2. Phytosanitary resolution: a systematic process to challenge scientifically unjustified phytosanitary regulations that adversely affects US seed exports.
3. Seed Health Method Development and Standardisation.

The accreditation component of the NSHS requires that applicant organisations, such as seed companies, seed certification agencies and consultancies, meet defined standards for facilities, equipment, personnel training, and methods. Standards are implemented by document review and site visits by trained auditors. Seed health methods used in the system are established by peer review, using technical panels of experts who ensure that the methods meet pre-determined criteria. USDA-APHIS then approves methods for publication in the NSHS manual of methods. To date, over 40 methods are published in the manual. Because some methods do not meet the minimum criteria for standard methods, a funded program has been put in place so necessary research can be carried out to enable acceptance of these methods as standards.

The phytosanitary resolution component of the NSHS utilises the CAB International Database on seed borne diseases to provide scientific information to resolve seed health issues that influence international movement of seeds. The program has also had excellent success in rationalising phytosanitary regulations in several regions of the world using Pest Risk Analysis.

Conclusions

The NSHS includes many of the components that would be desirable for a national plant diagnostic network.

The NSHS has a single coordination point (through a Seed Health Accreditation Manager), underpinned by a series of technical and policy groups. Having a defined coordination/oversight role is vital.

The system also operates on a cooperative approach between government agencies and key industry bodies, with the intention of meeting the needs of both interested and affected parties in regards to seed health. This helps ensure support for, and endorsement of the system by all key stakeholders.

Managing the requirements for sound science and policy and effective administration is another key area.

Relevant state and federal government plant health officials provide policy coordination on the overall system, and key stakeholder groups are engaged in providing technical expertise and information, and selecting expert technical panels.

Necessary scientific expertise is provided through expert technical panels, which are tasked with both proposing and reviewing seed health testing and field inspection methodologies. Peer review is an important part of developing methodologies. Once endorsed, approved methodologies are then incorporated into a single agreed manual of procedures and processes, which again provides for consistency and coordination of the overall system.

Day to day accreditation processes are managed by administration units, with responsibility for applications, audits, training sessions, proficiency testing, and record keeping.

A full description of the system and diagnostic method protocols can be found at the NSHS web site (www.seedhealth.org).

Resource management and funding challenges for plant diagnostics

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While the workshop covered a range of important topics in relation to the future of plant health diagnostics, it is also very important to look at the operating environment and those critical factors that will affect support for plant health diagnostics in the public sector.

In Australia, the public sector, (including state/territory agriculture agencies, the Commonwealth Department of Agriculture, Fisheries and Forestry - Australia (AFFA), and universities), supports the overwhelming majority of plant health diagnostics work.

This assessment is based on a recent PHA report that reviewed the human resources involved in plant health diagnostics (Moran and Muirhead, 2002). There are more private providers and they play a significant role, but the PHA report is based on 66 responding laboratories, of which only two were from the private sector.

It would be very useful to have better figures on participating laboratories, staff numbers and their expertise in diagnostic activities, priorities and workloads.

Clearly for Australia and New Zealand to continue to minimise the impact of plant disease on our agricultural industries, it is essential to know what the existing and potential resources at our disposal are. Governments and industry really need to work out what are the particular outcomes they are looking for from plant health diagnostics services, and therefore from a plant health diagnostics network. Without a clear and concise understanding of the requirements of a coordinated service, it is likely that both sectors are going to make inappropriate or inadequate resource allocations.

Competition for limited government resources

If we look at the most recent Organisation for Economic Cooperation and Development (OECD) assessments of government assistance (OECD, 2002), expressed through producer support estimates as a percentage of farm income, you can see that New Zealand and Australian government policy positions provide the lowest levels of support. While currently sitting at four per cent, this figure for Australia is down from nine per cent in the mid 1980s and for New Zealand, this difference is even more startling, dropping from approximately 11 per cent in the mid eighties to now only one per cent, compared with exceptionally high levels of support in the EU, US and Japan (see Table 1).

Table 1: *OECD estimates of government support to agricultural producers expressed as a percentage of income*

Country	*mid 1980s*	*2001*
New Zealand	11%	1%
Australia	9%	4%
Canada	33%	17%
USA	25%	21%
EU	42%	35%
Japan	62%	59%

While the rural sector in Australia and New Zealand (Ministry of Agriculture and Forestry, 2003) still represents 18 and 66 per cent respectively of all export income, the impacts of the sector on Gross Domestic Product (GDP) is only 2.6 and 5.4 per cent respectively. Moreover agricultural employment in Australia and New Zealand only represents 4.1 and 8.9 per cent of the total, with Australia being one of the most urbanised nations in the world. At the same time, compared with other OECD nations, Australia, in particular has a low level of taxation (relative to GDP).

These trends in governments' involvement in the agricultural sector are in keeping with the micro-economic reform that both countries have implemented over the past twenty years (Productivity Commission, 1999 and 2001). Consequently, all sectors of industry, including agriculture, in both Australia and New Zealand have had to develop strategies that allow them to compete globally, with minimal assistance from government (see Table 2).

Combining all of these issues, and the fact that both nations have a combined GDP which is approximately 2.7 per cent of the total of the EU, US and Japan means that Australia and New Zealand governments simply cannot afford to operate a large network of plant diagnostic laboratories at a level which is not in keeping with the needs and requirements of both industry and government.

Table 2: *Productivity Commission estimates of assistance to Australian industries over the last 30 years* (Productivity Commission, 1999 and 2001)

Sectors of Industry	*1969-1970*	*1979-1980*	*1989-1990*	*1999-2000*
Agriculture	27%	7%	8%	9%
Total manufacturing	35%	27%	16%	5%
Textiles, clothing, footwear and leather	-	-	85%	26%
Motor vehicles and parts	-	-	55%	15%
Petroleum, coal and chemicals	-	-	11%	4%

Changes to government priorities

Looking at the OECD's latest review of agricultural policies (OECD, 2002), the international focus of governments' policies (and therefore spending), is on

> *sustainable development, food safety, environment, rural development, the multifunctional role of agriculture, market concentration and competition policy.*

That is, governments are concentrating on those areas of delivery where there is market failure, and the private sector is unable, unwilling or incapable of meeting the requirements of governments or communities.

In some cases, businesses find certain operations unprofitable while, in others, governments are unwilling to expose the community to service provision by businesses that are solely focused on shareholder returns.

It must be recognised that there are considerable differences in the functional areas covered by the agricultural agencies in Australia. However, all governments are addressing natural resource management issues through their agricultural portfolios. Certainly, the NSW Government is placing a very strong focus and investment of resources on key environmental sustainability issues such as salinity, soil acidity, water use and efficiency, land degradation and native vegetation.

This increase in focus on the improved management of natural resources and the development of sustainable practices reflects the changing views of society at the end of the twentieth century.

Farmers are part of this process and in Australia today, these issues are the big issues facing the rural sector. NSW Agriculture has responded accordingly with its research and free extension service, changing to meet the changing demands of both industry and government. This change is part of an evolving process for an organisation now in its 114th year.

In the past, there were few alternatives to the Department of Agriculture as a source of information for farmers. This is no longer the case, with a large network of agronomists and technical staff either operating as freelance consultants or attached to the rural retail and distribution system across both Australia and New Zealand. These businesses provide sound up-to-date information in a range of technical areas where they are able to maintain a profitable business operation.

In New South Wales, (NSW) this has meant the Department's extension service is now focusing much more on those natural resource areas where there is market failure, and assisting farmers to deal with issues where there is no commercial alternative, but where the impact on their business, and on rural NSW, is significant. NSW Agriculture staff do this in the context of an in-depth knowledge of the particular farming system, and with the recognised respect and credibility of the organisation.

Relative importance of plant health diagnostics

When governments' make key funding decisions today they are not only looking for value for money, accountability and the recognition that it is correctly the role of government, they are also treating funding as an investment. More and more they are looking for short-term or key investments with long-term gains, and those gains are likely to be a reduced commitment to long-term expenditure.

Governments are shifting away from recurrent expenditure, to expenditure, or an investment, that will reduce long-term financial commitment. This is evidenced by the increasing role of private sector businesses in major infrastructure projects, with government funds being used strategically to initiate and maximise the benefits to the community.

The other key features that need to be demonstrated are sound planning, strategic, rather than *ad-hoc* solutions to real problems, appropriate risk management with shared investments, a clear understanding of how the initiative meets government responsibilities for delivering services to its community, and how this initiative fits into the national context.

The reaction of governments to the outbreak of Foot and Mouth Disease (FMD) in the UK in 2001 is interesting to look at in light of this workshop. Various Australian governments responded with significantly increased commitment of resources to emergency animal disease preparedness during 2001-2002. This was in response to heightened awareness of the potential impact of an outbreak of FMD on the agricultural sector, the Australian economy, and employment statistics.

The Productivity Commission predicted (2002) that an outbreak of FMD in Australia could lead to a 3.5 per cent drop in GDP, one per cent rise in unemployment and international trade reduction of $5.8 billion. These impacts struck home to government, the Australian community and politicians. Of course, tied up in that response, were concerns about the trade and domestic public health impacts of Bovine Spongiform Encephalopathy (BSE) or mad cow disease.

Is there potential for coordination of plant diagnostics across Australia and New Zealand?

The answer to that question is clearly, yes.

I would like to use NSW as an example. Plant based agriculture in the state has undergone considerable changes in the last 40 years. Traditionally, agriculture extended from the wheat belt, east to the coast. The wheat belt itself has been extending west into drier areas with now approximately 50 per cent of NSW's wheat crop grown west of the Newell Highway, with a rainfall of less than 500mm per year.

Agriculture in those areas has also expanded with the development and expansion of oilseed, pulse, cotton and rice industries. Significantly, there have also been new developments in horticulture and viticulture, particularly along the western rivers, which had long been seen purely as a pastoral zone, and new horticultural and nursery based industries on the north coast, as land prices and lifestyle changes have forced dairy and pig producers inland. NSW has a wide range of plant-based industries due to the diverse climate of the state, including subtropical horticulture and sugar cane, cool climate pome fruit and viticulture, dryland cereal production, and an extensive range of irrigated industries.

Currently, NSW Agriculture has 66 district agronomists and 35 district horticulturists working across these industries. Together with 40 animal and plant regulatory staff, these officers serve as a front line, operating as the “eyes and ears” of the organisation. We also have about 200 research staff working with the plant-based industries. We also have 30 officers with various skills and expertise working in plant health diagnostics across those industries. The skills base covers general pathology, entomology, microbiology, virology, mycology, nematology and taxonomy.

Some years ago, NSW Agriculture decentralised its plant health diagnostic service, placing specialists in key Centres of Excellence across the State, and closer to the field staff, research programs and industries they service. We now have specialist services across the major production areas. There is one dedicated general laboratory, Elizabeth Macarthur Agricultural Institute, (EMAI) at Camden on the southern outskirts of Sydney, and a number of generalist pathologists and specialist support services located in Tamworth, Narrabri, Wollongbar, Orange, Wagga Wagga, and Yanco.

The only way that this structure can deliver objectives is through clever networking of services.

Clearly, there is a balance to be struck between locating diagnosticians at facilities across a network and in proximity to the researcher and industry, and having a large centralised and efficient laboratory. Experience in NSW in managing two regional veterinary laboratories and one co-located at EMAI along with the centralised specialist laboratories, has shown that a networked service can operate extremely efficiently with modern and efficient low cost transport and electronic communication.

The challenges to be faced in achieving this within a state as large and diverse as NSW are generally the same as the challenges that could be expected in providing a diagnostic network service across Australia and New Zealand. Maintaining standards, proficiency and resources, cost recovery and cost sharing, service delivery, information management systems, confidentiality, and in some cases intellectual property, are all issues to be considered.

One further matter that must be considered is the requirement by jurisdictions to be self-sufficient. For larger jurisdictions this is probably not a burden, as the laboratory will have the diagnostic throughput and range of material necessary to maintain the skills and expertise necessary to operate a diagnostic laboratory efficiently.

For smaller jurisdictions it does become an issue and clearly some mutually contracted arrangements should be developed amongst jurisdictions to ensure adequate service across Australia and New Zealand.

Specialisation and a national responsibility for specific diagnostic procedures being attached to various laboratories is a matter for consideration.

As already noted, before you begin designing a network, you need to clearly define the desired outcomes of the system, and determine how those outcomes are best resourced.

Private versus public good in plant diagnostic capacity

As indicated already, there is ongoing competition for limited government resources, and those resources must be allocated on the basis that there is no alternative service provider, and that the benefits from investment will accrue to the community as a whole.

Clearly private plant and animal diagnostic laboratories exist, but often only providing a limited range of routinely sought analyses where there is opportunity to operate a profitable business. As a result, there is market failure for a wide range of plant and animal diagnostic procedures and governments provide services to assist industries where there is no alternative, and in some cases where failure to detect a disease may have widespread implications for the community, for example zoonotic diseases.

In the provision of a plant diagnostic service, as in animal diagnostics, NSW Agriculture has endeavoured to identify the beneficiaries of these services.

Beneficiaries can be individual farmers or businesses, the industry as a group or the whole community. Accordingly, NSW Agriculture has indicated that where the beneficiary is an individual farmer or business that the full cost of the service provided should be paid by the client.

In some cases this is quite straightforward, for example, in the analysis of blood samples from cattle destined for live export to ensure they meet overseas market access requirements. Clearly, the beneficiary is the exporting business, and as such, it should meet the full cost of the service.

Where diagnosis of a disease may have industry wide or community wide implications, NSW Agriculture's policy is to undertake such testing free of charge, or at a subsidised rate. This is justified on the broad financial benefit to the community of NSW. For example, all specimens submitted as potential zoonotic disease, notifiable diseases under the *Stock Diseases Act (1923)* or the *Plant Diseases Act (1924)* and possible exotic disease incursions are tested free of charge.

In cases where industry wide programs have been established, and where clearly there are financial benefits to the producer from undertaking laboratory tests, a subsidised fee structure has been negotiated. Examples in the animal diagnostic service include tests for ovine footrot, ovine and bovine Johne's disease, and enzootic bovine leucosis.

Veterinary laboratories comprise the major component of NSW Agriculture's diagnostic laboratory service, representing 84 per cent of the financial and volume turnover, compared with less than five per cent for the plant diagnostic service. Chemistry services make up the remaining 11 per cent. Fee-for-service income accounts for $2.2 million of the total cost of $4 million to operate the diagnostic laboratories.

Similarly as a means of addressing the cost of controlling exotic animal diseases in Australia, Animal Health Australia (AHA) has categorised 63 exotic animal diseases affecting a range of animal species as part of the cost sharing agreement entered into between all Australian governments and the animal industries (Animal Health Australia, 2002). These diseases are categorised on their potential to impact either on the individual business, the industry or the Australian community, and the proportion of government (state and Commonwealth) funding which is allocated to the eradication is proportional to the impact on the community.

For example, the eradication of rabies would be fully funded by governments, FMD funded 80 per cent by government and 20 per cent by industry reflecting that industry will accrue some benefit, Newcastle Disease of poultry funded 50 per cent each by government and industry, and Equine Influenza 20 per cent governments and 80 per cent industry.

While these definitions, in terms of who the beneficiary is, set a guideline for a charging structure in diagnostic laboratories, experience in NSW, particularly within the animal health laboratories, has shown that it is important for government laboratories to maintain a core level of expertise.

This means staffing levels with highly trained pathologists are often greater than compared with in a commercial laboratory only undertaking routine private sector functions. It is also essential to maintain a throughput of material, which is varied and covers the full spectrum of analysis to ensure the skills of staff are adequately maintained. The cost of maintaining these skills and expertise cannot be passed onto clients paying a fee-for-service and must therefore be considered as part of the cost to be met by government.

At the same time, there is a requirement to ensure field staff are appropriately trained. NSW Agriculture has provided funds to enable district agronomists and horticulturists to submit material for laboratory diagnosis that they may be uncertain about, but for which a farmer may not necessarily be willing to pay for the associated laboratory charges. This is particularly targeted at less experienced field staff so as to ensure they develop their field diagnostic capabilities.

Further comparisons with animal diagnostics

Recognising that there are great differences between the worlds of animal and plant health diagnostics, this workshop is a good opportunity to look at the systems and drivers behind animal health diagnostics.

Animal disease control is heavily driven by trade. The international animal health agency, the Office International Des Epizooties (OIE) has among its goals ensuring the sanitary safety of world trade by developing sanitary rules for international trade and guaranteeing the transparency of animal disease status worldwide (OIE, 2003). Member countries undertake to report animal diseases as detected. The OIE then disseminates the information to other countries, which can take the necessary preventive action.

This requirement covers a standard list of 79 livestock and bee diseases. OIE also publishes diagnostic standards.

Individual countries are required to report on the presence of disease and maintain a disease detection capability. This has certainly been a driver behind the development and maintenance of animal health diagnostic networks in countries like Australia. To meet these reporting requirements in Australia, each state/territory either runs or contracts field and diagnostic laboratories and provides quarterly and annual reports for national collation by the Commonwealth through AFFA.

In NSW Agriculture there are 24 animal health generalists, and specialists, including epidemiologists, working in animal health diagnostics. The field staff drawn from the Department and the Rural Lands Protection Boards comprise of Advisory and Veterinary Officers, Research Officers, Regulatory Officers and Rangers. As far as disease diagnosis, private veterinary practitioners make a significant contribution to fieldwork and laboratory submissions.

The animal health reports cover a wide range of diseases including a range of endemic diseases, the most significant exotic diseases, and emerging diseases. Reporting is based on mandatory notification requirements under state legislation. There are currently 110 notifiable diseases of domestic animals and bees in NSW.

Coordination of animal health programs is provided by AHA and through the Animal Health Committee (AHC) of Primary Industries Standing Committee. An AHC subcommittee deals with animal health laboratory standards, maintains a set of Australian standard diagnostic techniques, and approves new techniques. It was also charged with establishing and maintaining a national laboratory quality assurance (QA) program.

Australian animal health laboratories in the public or private sector wishing to undertake export testing are required by the Australian Quarantine and Inspection Service (AQIS) to have accreditation by the National Association of Testing Authorities (NATA). With this requirement comes the need to demonstrate proficiency. In support of accreditation, proficiency testing programs have been established for serology, bacteriology, parasitology, and for anatomic and interpretive pathology.

The animal health laboratories subcommittee is also charged with nominating and monitoring the performance of national reference laboratories for the specific diseases.

The Australian Animal Health Laboratory (AAHL) is of course, the reference laboratory for exotic livestock diseases. The national reference laboratory for Tuberculosis is located in Western Australia and the NSW laboratory at Camden is the reference laboratory for Anthrax. Animal diagnosticians also use the National Salmonella reference laboratory in South Australia.

These reference laboratories charge for their services. The AAHL charges for commercial export/import tests but not for diagnostic testing for exotic diseases.

AAHL also undertakes research to develop new diagnostic tests, vaccines and therapeutics for endemic animal diseases of national importance. Work at AAHL covers the major diseases of livestock, aquaculture animals, and wildlife.

Conclusions

Governments will continue to have competing demands placed on their limited resources, and a plant diagnostic network will have to be part of this competitive process. Accordingly, in establishing a plant diagnostic network for Australia and New Zealand the outcomes of all participants need to be clearly articulated.

Industry must be willing to make appropriate financial contributions to ensure the network is viable, and industry and government need to undertake risk management assessments for various crops and disease to assist in the correct allocation of resources.

Services currently being provided in both public and private sector laboratories across Australia and New Zealand need to be assessed with a view to creating efficiencies, and the adequacy of staff training and technical expertise needs to be evaluated/assessed across the proposed network, both in terms of laboratory and field diagnosis.

The consideration of contractual arrangements among potential network participants needs to be examined, along with the possibility of identifying laboratories with recognised national significance.

Finally, a mechanism similar to the subcommittee of Animal Health Laboratory Services will most likely be required to ensure appropriate levels of accreditation, quality control and training are addressed.

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THE NEED FOR ACCREDITATION
OF LABORATORIES AND TRAINING REQUIREMENTS

Accreditation in Plant Health Laboratories - the challenges of seeking accreditation

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Introduction

Why should plant health laboratories seek accreditation? The glib response would be 'because everyone else is doing it!' In Australia, water microbiology and medical laboratories have been accredited for many years, medical pathology laboratories undertaking the HB 18.25: 1999 (Guide 25) accreditation for 12 to 15 years as required by the Medibank and Medicare systems.

In an agricultural context, the move towards accreditation of diagnostic laboratories commenced in 1996 with the issuing of *Supplementary Requirements for accreditation in the field of veterinary testing* by NATA. This document supplements Australian standard ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories* that superseded Guide 25. Most animal health diagnostic laboratories are now accredited to this international standard. Only two plant health diagnostic laboratories are accredited to this standard, under the *Supplementary Requirements for accreditation in the field of biological testing*. These are the Department of Primary Industries, Water and Environment (DPIWE) ELISA pathogen testing service, accredited in May 1994 and the Camden laboratory of the Plant Health Diagnostic Service, NSW Agriculture, accredited in October 2001. Another laboratory is accredited under the ISO 9000 series and six have other types of systems (unspecified) in place (Moran and Muirhead, 2002).

Two developments in the last 12 months have come together to stimulate interest and discussion of accreditation in plant health laboratories in Australia. These are the ongoing negotiations between industry and government members of PHA towards a cost sharing agreement to deal with eradication of exotic plant pests and diseases (Plant Health Australia, 2002a) and PHA's *Development of Specific Diagnostic Capacity* project, which was established to develop diagnostic protocols for selected exotic plant pest organisms (Plant Health Australia 2002b). Increasing costs of eradication and the shift in emphasis from fully government funded eradication programs, to a notion of a government/industry partnership (with the proportion of funding paid by each party dependent on the category of the incursion), puts more emphasis on the use of valid test procedures and the competency of the reporting agency to carry out the tests. One way of providing assurance that a particular laboratory has correctly identified an exotic disease is through participation in an appropriate accreditation scheme. A move to accreditation of plant health laboratories in Australia has commenced.

Two laboratories have accreditation to ISO/IEC 17025:1999 (through NATA) and another to the ISO 9000 series. A description of other possibilities is provided in the workshop paper of PHA Program Manager Rodney Turner.

This paper outlines some of the reasons for gaining accreditation. Challenges such as cost, change management in the laboratory and provision of proficiency testing programs in plant health sciences are discussed, as well as why accreditation may be financially advantageous in the current climate prevailing in plant health policy development (at least in Australia).

Options for accreditation

From the author's perspective, two major possibilities exist for accreditation. These are accreditation to ISO 9000 series or ISO 17025:1999.

ISO 9000 series

In this internationally recognised system, certification to ISO 9000 series implements quality management principles which vary in scope depending on the particular standard in the series. There are a maximum of eight principles which cover customer focus, leadership, involvement of people, process approach, systems approach to management, continual improvement, factual approach to decision making, and mutually beneficial supplier relationships. It is important to note that Individual tests are not accredited in this system. The focus is on product realisation through design and development verification.

ISO 9000 series can be applied to any industry, from car manufacture, to paint production, to an accountant's office. It covers the system/consistency of operations but does not apply to the technical validity of any of these processes. Therefore, it can be used in research laboratories. The focus is on planning and reviewing, and the associated records. Instead of controlled processes, there is a need to include checks and balances to ensure everything is accountable and traceable. The orientation of this ISO series is towards customer satisfaction, where funding bodies or the managing body of the laboratory may be the customer.

This standard needs less documentation as part of its requirements, and is much more open to interpretation, but evidence of the management of the system is still required. However, it has no requirements for technical proficiency programs.

ISO 17025:1999

ISO/IEC 17025:1999 is also recognised internationally, and represented at the General Assembly of the International Laboratory Accreditation Cooperation (ILAC) by NATA in Australia. The standard embodies all the management principles of the ISO 9000 series, and in addition requires demonstration of technical competency and technical validity of results. This standard dictates, and details, the management system and the technical aspects of the testing. Calibration services offered and used must all be documented. Proficiency testing, quality control and method validation are necessary parts of accreditation.

ISO 17025 is specific to testing and calibration laboratories, ensuring that the laboratory is competent in the work it is undertaking. This competency includes testing, equipment and staff. It is stringent and specific in its requirements. The research processes of a laboratory cannot be accredited, but, if part of research is to conduct surveys using standard or published and validated diagnostic techniques, then accreditation may be warranted. Routinely practised procedures like media preparation, culture or PCR, may fall into ISO 17025, but not research. It could cover PCR, but not a hypothesis or what is being investigated. In a diagnostic lab, the actual test method can be accredited.

Supplementary requirements, published separately, must be met under ISO 17025, depending on the discipline being accredited. There are supplementary requirements for biological, veterinary and chemistry laboratories. The most appropriate accreditation for plant health diagnostic laboratories comes under the biological testing requirements of this standard.

ISO 17025 requires approved signatories to authorise test results. These people are usually senior staff (e.g. experienced professional officers). NATA auditors interview potential signatories during the assessment process to confirm their expertise. The auditors are always senior members of their profession and provide valuable feedback to staff during this process.

Because of its greater scope, with both management and technical requirements, ISO 17025 has been chosen as the most appropriate system for DPIWE laboratories. The management and technical requirements of the basic standard are listed at Table 3. Supplementary requirements are prescriptive of attributes particular to the type of testing. For instance, in-house media preparation and quality control is given particular attention with a list of the records that must be kept of the preparation details for all types of media.

Table 3: *Management and technical requirements of ISO 17025*

Management Requirements	*Technical Requirements*
Organisation	General
Quality system	Personnel
Document control	Accommodation and environmental conditions
Review of requests, tenders and contracts	Test and calibration methods and method validation
Subcontracting of tests and calibrations	Equipment
Purchasing services and supplies	Measurement traceability
Service to the client	Sampling
Complaints	Handling of test and calibration items
Control of non conforming testing and/or calibration work	Assuring the quality of test and calibration results
Corrective action	Reporting the results
Preventive action	
Control of records	
Internal audits	
Management reviews	

The timeframe for accreditation to ISO 17025 means the process is not for the faint hearted. From start to finish, given sufficient resources, the process can take two or more years to be completed. For example the Animal Health Laboratory at Mt Pleasant, Tasmania made its first enquiry regarding accreditation during 1997 or 1998, but did not achieve accreditation until August 2001. The major steps along the way, following the initial enquiry, include an advisory visit (May 1999), formal application, document review, and assessment (November 2000), and eventual accreditation. The DPIWE ELISA laboratory, the first plant health virology laboratory to be accredited in Australia, took longer. An advisory visit occurred in July 1990, the initial audit in September 1991, a follow up audit in 1993, and accreditation was achieved in May 1994.

In 1999, NSW Agriculture adopted a policy that all diagnostic laboratories were to be accredited. Veterinary laboratories at three locations developed and gained accreditation to ISO 17025. NSW Agriculture Plant Health Diagnostic Laboratory at the Camden location made its first enquiries in 1999. Because no other plant pathology laboratory had sought this level of accreditation, working closely with NATA the first written enquiries began in December 1999. The documentation and application was presented in 2000 with the assessment visit in early 2001 and accreditation being granted in October 2001.

There are many 'behind the scenes' activities that must occur so that the basic milestones of advisory visit, application, assessment and accreditation can be achieved. As a guide to other laboratories contemplating the accreditation pathway, some of these activities are listed as an attachment to this paper.

Following accreditation, reassessment is required approximately every two years, and participation in proficiency testing is usually required. The latter has proven difficult in the plant health area. In the absence of proficiency testing or a quality assurance (QA) program for ELISA testing, all testing uses both positive and negative controls. However this does not achieve the aims of a properly conducted independent proficiency testing program (further discussion of proficiency testing appears under the heading, *challenges of seeking accreditation*).

Benefits and disadvantages of accreditation

While there are challenges in establishing an accredited quality system in plant health diagnostic laboratories, which will be discussed separately, the significant benefits all come from operating within a systematised environment. All diagnostic laboratories have systems, which deliver results to clients. Such results should be the product of good science delivered in a controlled manner with consideration of client needs. An accredited quality system can demonstrate this, and meet client requirements by providing test results from validated test methods run in a systematised environment. It is apparent from Table 3 that a system of checks and balances forms the core of a quality system, adding value to the test results of any laboratory.

There are several key elements in any quality system which benefit the accredited laboratory. These address the sample, the test, client needs, and the ability to improve the system on an ongoing basis. In addition, risk management and promotion of external recognition are important benefits.

Sample

A quality system requires sample tracking from accession to sample disposal. Questions concerning sample management can be readily answered. For instance, are samples stored correctly? How long has the sample been stored before testing? Has the correct sample been tested? Has the test (or range of tests) requested or deemed necessary for diagnosis been undertaken and completed? What is the ultimate fate of the sample?

It should be noted that one of the few limitations is application of the system only once the sample reaches the laboratory. There is no control of initial sampling techniques, but laboratories can of course make recommendations to clients.

Test

When considering those factors influencing the testing of samples in the quality system, all aspects of the test that can impact on the result are controlled. Purchasing and supply of reagents ensures that validation of quality, and consistency of batch is evaluated. The quality control of media preparation is monitored and validated. Do the media grow the organisms they were designed to grow? Will media inhibit organisms they are designed to inhibit? Quality control of batches of prepared media, using standard organisms, will verify this.

Tests are often reliant on the correct functioning of equipment (e.g. pH meters, incubators). A quality system provides a method to check that equipment is working to its specifications through monitoring and calibration, such as recording the temperature in incubators or pipette calibration to assess delivery of volume. The quality system has a developed method for managing situations where equipment or results are found to be outside the expected range.

Staff skills are important in the delivery of a validated test result, and for that reason, staff undertaking tests need to be assessed for competency in the tests that they deliver. Where competency is found to be lacking in support staff, this can form the basis for identifying training needs.

Where test results fall outside the normal or expected range, a quality system provides a method to identify these and outlines predetermined actions to deal with those results. It also initiates a tracking system to ensure that spurious results are investigated and the results analysed so that errors are not repeated and are eliminated from the system.

Client needs

Client service forms part of the delivery of a quality system. This is served by proving transparency of laboratory actions and responses as part of improved client relations (e.g. a client can ask to see your facilities, or ask you to outline your test methods). A marketing advantage may well flow from this aspect of the quality system. No client of a service wishes to have results that could be incorrect because of lack of adherence to procedures. Client service is also addressed in complaints handling. The system requires a method of tracking and recording complaints. This feeds in to one of the principal aims of any quality system - identifying areas for improvement.

Improvement

Continuous improvement of the laboratory's capacity to deliver consistent results forms a cornerstone of the system. Auditing all aspects of a diagnostic system and undertaking corrective actions, where system failures are found, provides a method of improving laboratory activities. The highest level management, which controls laboratory activity, is involved by playing an active part in the quality management review, usually on an annual basis.

Risk management

The resultant, overall benefit to the diagnostic service of adoption of a QA system, in an increasingly litigious society, is the reduction of risk of claims in law. Participants of quality systems have enhanced reputations as individuals, for the laboratory and for the organisation. It provides recognition from internal and external bodies that a quality system is in place.

ISO 17025 is a performance-based accreditation system, demonstrating competency, the production of technically valid results and all aspects of the test including management, equipment, staff, and environment are controlled. Therefore, the risk of producing inaccurate or incorrect results is significantly reduced. In the advent of litigation, all aspects of the testing process are documented.

External recognition

ISO 9000 series and 17025 are both recognised worldwide. However, the advantage of adopting accreditation to 17025 may be found in terms of international trade. An international arrangement to enhance trade was signed and came into force from January 2001. The international trade agreement involved 37 accrediting member bodies from 28 economies represented at the General Assembly of the ILAC. Re-testing of goods by an importing country has been a major technical barrier to trade. The ILAC has been working to overcome these technical barriers and this arrangement will facilitate the acceptance of goods already tested by an accredited laboratory. The key to the arrangement is the assessment of an individual laboratory as being competent by laboratory accreditation bodies.

Staff comments on the value of accreditation

In addition to the above areas of benefit, some of the immediate benefits that come from moving to an accredited quality system are apparent in comments of staff that have been involved in the process. In the DPIWE Animal Health Laboratory we are producing better results simply through staff being obliged to go back to the original test methods in preparing standard operating procedures. It was a revelation to some staff to find that repeated verbal training in execution of a particular test can lead to inaccuracies in the methodology. Peer auditing during the assessment, although potentially intimidating, has been invaluable in raising awareness of isolated staff to current test methods. Staff from other accredited laboratories say that cultural change and improved quality, increased customer focus and timeliness of reports, and benefits to staff and clients have also been a big plus.

Internal auditing highlights compliance with the standard, further increasing staff confidence in the results they are issuing. Staff also have increased confidence in their work, with greatly reduced chances of unforseen results. Accreditation provides the DPIWE ELISA lab with a significant market advantage in virus identification.

Disadvantages

The disadvantages of a quality system can be outlined in terms of its greatest benefit. The system is document based, and establishing necessary documentation can be costly and time consuming, hence the timeframe to accreditation outlined earlier.

Recording is also something that may involve initial resistance, until a cultural change occurs and all recording activities become routine. Maintaining the system is time consuming. The rigid requirements for quality control on media for example, may translate to requirement for higher staffing levels or rearrangement of work loads. Therefore introduction and maintenance of a quality system needs the ongoing support of senior management.

Challenges of seeking accreditation

The biggest challenges of seeking accreditation come from change management, the cost in terms of dollars and resources and, once accredited, the cost of participating in proficiency testing. An added challenge for plant health diagnostic laboratories is the development of appropriate proficiency testing programs. Another issue that must not be overlooked is validation of newer technologies of molecular diagnosis, particularly for exotic organisms under Australian conditions.

Laboratory management needs to adopt and implement change management strategies, suited to its workforce. Staff may be unfamiliar with the concepts and language of quality systems; it can therefore be a frightening prospect. Staff need to examine their current procedures in terms of the standard with which they seek to comply. They will also need to make the necessary changes to their work or documentation in order to fulfil the requirements of the standard.

In addition, managers who also have not been exposed to "quality culture" may find themselves feeling a little lost with the concepts and language and may also be afraid to admit that they have limited knowledge of what is required. NATA offers training courses including an introduction to laboratory accreditation requirements and quality management in the laboratory that would assist in this process. The NATA website (www.nata.asn.au) provides additional details on these courses.

NATA costs (2002-2003) in terms of fees and charges payable to an accrediting body are provided at Table 4. For advice on fees applicable to your situation contact the NATA office in your state or the accrediting body in your country. NATA advise the most cost effective way in consultation with their prospective clients. This organisation works on the basis of cost recovery only.

Table 4: *Extracts from the NATA 2002-2003 fee schedule*

Fee type	*Item*	*Cost ($)*
Application Fees		
	Application Fee	1550 plus GST
	Advisory Visit	155/hour plus GST
	Documentation Review	155/hour plus GST
	Initial Assessment	155/hour plus GST
Annual Membership Fees		
Base Fee	1 technical unit	2335 plus GST
	2 technical units	3625 plus GST
	3 technical units	4915 plus GST
Zone	Distance from GPO	
1	0-100km	Base Fee
2	100-200km	Base Fee + 5%
3	200-750km (includes Tasmania and ACT)	Base Fee + 10%
4	750-1500km	Base Fee + 15%
5	Over 1500km (includes NT)	Base Fee + 20%

All preparation for on site visits, report writing and post assessment activities are charged at the hourly rate. In addition to the fees in Table 4, all travel, accommodation and associated expenses are charged at cost. An advisory visit usually takes three or four hours. The term 'technical unit' is a measure of the assessment effort required to service an accredited laboratory.

In addition to the direct costs outlined in Table 4, there is a range of indirect costs that will also be incurred. Existing staff must be relieved of enough of their existing duties to develop the necessary documentation initially and then to provide management of the quality system, conduct quality control of test and test processes, and carry out the necessary calibration and monitoring of equipment. Participation in quality assurance programs also has a cost associated with it in staff time for participation and charges payable to the program coordinators. However the benefits of participation in terms of staff morale and confidence, and overall confidence in the results produced by an accredited laboratory cannot be reliably measured, but far outweigh any drawbacks.

Proficiency testing is based on QA programs run by a number of organisations with varying associated costs. All QA programs are structured similarly. Spiked samples or samples with established values are sent to participating laboratories monthly, bimonthly or quarterly. After testing, results are returned to the convenor and some time later, a report is provided showing results statistically compared with other participants. A report must be provided to the program convenor if the laboratory failed a test or produced an outlying result.

The biggest challenge for plant health diagnostics, worldwide, is to develop and contribute to proficiency testing programs for established pests and diseases in the first instance and exotic organisms secondly. On the plant scene there already exist laboratories which will run proficiency testing programs for other laboratories undertaking diagnostic testing for nutritional status in plants. This is a chemistry-based program. However, at this time, no provider exists to conduct proficiency testing for plant viruses, fungi, bacteria or insect identification. For bacteria it may be possible to expand the system provided by suppliers such as IFM Quality Services P/L, in which case histories and associated freeze dried samples are provided to participating laboratories. It is understood that technical issues would need to be resolved, even for this to happen, but some preliminary discussions have occurred.

To establish QA testing for plant viruses, the problem of supply of viable and consistent samples to participating laboratories must first be overcome. No single organisation can tackle the developmental work necessary to resolve this problem without the provision of funding.

There will be difficulties in establishing a QA program for pests and diseases already established in Australia. This is compounded for the diagnosis of exotic pathogens by Australian laboratories where quarantine concerns will preclude the distribution of viable material. Because of the expense and risks associated with such an approach, exchange of staff with overseas laboratories, skilled in the identification of the target organism, could be considered, rather than the distribution of diseased material within Australia. A program for adult stages of insect pests, both established and exotic, would be easier to establish because of the methods used in preparation and storage of insect specimens.

Molecular diagnosis is a young discipline that must not be seen as the only tool in the box for identification of any particular organism. Such test methods must be fully validated, under Australian conditions, before taking their place in the toolbox. Morphological testing, isolation and identification of bacterial and fungal pathogens can be followed by molecular diagnosis. This validation of molecular diagnosis can be tested against existing taxonomic tools to sub-species level. It is vital that the importance of all tools in making a correct diagnosis be recognised and used to ensure that the diagnosis is in fact correct.

We understand that many laboratories acknowledge the challenge. They are keen to develop and implement proficiency testing as a method of validating results, but funding and lack of an existing program are major drawbacks to its development and implementation.

Training

Accreditation needs to be supported by trained staff and ongoing training requirements. Training can be formal and/or informal; however some system must be in place within the quality system to recognise training needs and record training where it has been supplied. Training can be in terms of the quality system itself or to improve staff skills base. Recording of training must be done and task competencies assessed. All training must be documented so staff can have the opportunity to assess and improve their skills, and management of processes can be made more efficient.

Quality systems training

Quality systems training involves training in laboratory quality management and audit procedures. Courses designed for managers and quality officers who will be involved in the establishment and management of quality systems are available. Such courses would cover the documentation of the laboratory quality system and maintenance through audits, system reviews and corrective actions. It should also cover management of equipment, testing environment, procedures, test items, safety, quality control, and records and reporting. Mention has already been made of the courses provided by NATA.

Audit

Training for all staff is an essential part of the accreditation process. This can be done formally at training courses, and informally in the workplace as a normal part of the quality process. Auditing is a skill that will equip staff to be positively critical of processes and more appreciative of the quality system.

Competency for individual staff performing a task has to be established and ongoing training needs to be provided as a matter of importance to the quality system. Recording of training must be done and competency assessed.

Skills based training

The identification of training needs lies with the management of the system. Training can be in terms of short courses provided through Technical and Further Education (TAFE), manufacturers and suppliers, or universities. Training can be achieved through continuing education, attendance of national and international courses and conferences, meetings of interest bodies, and visits to other laboratories.

Conclusion

No professional scientist or technical officer should be afraid of an accreditation process for the laboratory in which they work. That accreditation equals good science and is merely a formalised peer assessment process. Adoption of a quality system, demonstrated by accreditation, benefits a laboratory because of the systemised control of samples and tests. Client needs are more closely met and the system itself has a process to follow to improve the activities of the laboratory. Clients may choose to deal with laboratories which adhere to QA systems as the benefits of competency are increasingly demonstrated. This, combined with enhanced risk management, makes the adoption of QA a benefit to any diagnostic service.

There may be no financial advantages to be had, except the dubious one of gaining market share for testing, but there are other drivers appearing which may add momentum to the accreditation of plant health diagnostic laboratories in the future. While of no direct financial advantage to the laboratory concerned, these drivers do have financial overtones, but more for the potential clients. Australian consumers of plant diagnostic services currently have limited appreciation of the true value of an accreditation system. In the future, participants in the plant health cost sharing agreement may insist on accredited laboratories being used to provide the definitive identification of an exotic pest or disease before action is implemented. It may be envisioned that trade agreements with overseas countries may also reveal the value of accreditation.

Industry groups, in their endeavour to seek overseas and interstate markets, may come to be the drivers of the need for accreditation for disease diagnosis, particularly when establishing disease freedom is proving to be a trade barrier. However the true value of gaining accreditation for plant diagnostic services lies not in gaining financial advantage, but in the many other advantages of accreditation that have been detailed throughout this paper.

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'Behind the scenes' activities towards accreditation

Gain support from senior management:

- investigate most appropriate quality system;
- assess and present costs;
- arrange for information sessions for senior management; and
- confirm commitment from senior management of proposed quality system.

Inform staff that change is about to take place:

- arrange for staff training in the broad principals of a quality system;
- explain the change from a knowledge/skill/personal expertise base, to a documented, continuous improvement base;
- outline aims; stress that adoption will demonstrate that the laboratory has changed and operates a quality system;
- explain that the system will demonstrate competency and that the laboratory is able to generate technically valid results; and
- highlight that adoption may give a market edge and will give assurance to results.

Choose a supplier:

- investigate the market and assess the most appropriate accrediting body (e.g. Quality Society of Australia). Each quality system gains accreditation by being audited by the accrediting body; and
- choose the quality system most suited to your needs

Inform staff that the supplier has been sourced:

- highlight that a system is currently in place and running now;
- stress that it is necessary that the existing system be documented;
- have the laboratory document all procedures;
- explain that the next task is to change procedures and systems to comply with the chosen standard; and
- stress that the system will reflect and enhance the nature of the laboratory.

Arrange for key staff to take advice from the supplier:

- choose staff who can influence the work place;
- outline the particular laboratory requirements to the accrediting body;
- take advice on how the system might best be structured; and
- confirm price with supplier.

Implement changes required:

- provide quality systems training for key staff;
- arrange for one officer to be nominated as the quality officer, and provide this individual with extensive training;
- network with other laboratories that have undertaken the accreditation process;
- ask all key staff initially nominated to disseminate information to staff in their control or influence;
- monitor that staff are informed and involved; and
- deal with the conflict of getting the job done vs. adopting and implementing the quality system.

Take the QA standard or written requirements and break into small parts:

- take these parts and allocate tasks for individuals or groups to complete;
- set time frames - define process; and
- ensure that the quality officer consults with staff frequently to ensure that staff "own" the system - encourage and enable all staff.

Ensure that the quality officer controls all documentation:

- quality officer is to bring together the small parts of the system developed, then edit and consolidate; and
- arrange for the production of a quality manual. This then acts as a directory to the proposed quality system (sections1-4 of ISO 17025).

Arrange an audit schedule:

- ensure auditing is a critical part of the quality system;
- train key auditors;
- have trained lead auditors undertake audits with other staff as part of training; and
- allocate audit tasks to individuals with completion dates.

Implement the new system including:

- continuous improvement elements
  - auditing
  - identification of compliance with the standard;
- recording and archiving;
- improvement opportunities;
- corrective action;
- verification and recording action to correct non-compliance;
- addressing customer needs and complaints;
- statistical validation where possible and understanding of variation;

- quality management, including
  - overseeing reports and results
  - overviewing quality management meetings
  - addressing all non-conformance with the standard; and
  - developing strategies to overcome identified non-conformance.

Report to senior management:

- provide regular progress reports; and
- ensure explanation of reports and their continuing role in the implementation of the quality system, as changes to the workplace may affect senior management roles and responsibilities.

Empower staff:

- operational staff are vital to producing and implementing continuous improvement and must be informed and empowered through the whole process; and
- ensure this remains a continual process in the maintenance of a quality system.

Arrange for the accrediting body to undertake an inspection of the system

- this can take more than 6 months to arrange and involves:
  - producing documentation that supports the quality system involved;
  - arranging for a physical inspection of the processes against the documentation; and
  - making changes to documentation or processes as appropriate.

Comply with requirements to maintain accreditation:

- initiate self-assessment based on:
  - internal audits
  - corrective action
  - opportunities for improvement
  - quality management review of the system; and
- allow the laboratories to identify the principal areas of opportunity for further improvement within the existing quality structure.

Accreditation and training requirements of diagnostic laboratories

Rodney Turner

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Introduction

This paper covers the structural aspects of developing and implementing an internationally recognised accreditation scheme, including some of the types of accreditation available for diagnostics laboratories in Australia, including personnel accreditation.

Why establish an accreditation system?

The question of why set up an accreditation system has been asked on a number of occasions. Many diagnostic practitioners believe the current Australian system works well and that there is no need for "an additional bureaucratic overlay" and that the cost of getting, and staying, accredited is prohibitive. To answer this question one should look at similar types of operations overseas and examine if they have established an accreditation system, and if so, why. These issues were explored in some detail during workshop discussions on this topic. Many attendees were familiar with the ISO systems, which have a well defined structure of documentation and an auditing scheme built around them, but most were unaware of the alternative specialist accreditation schemes which could be adopted by plant diagnostic laboratories.

The International Seed Testing Association (ISTA) seed testing scheme was referenced as an example of a scheme that could achieve the outcome desired by Australian laboratories, but without the documentation complexity of the ISO system.

After general discussion, the workshop agreed that if decisions are to be made to undertake expensive exotic pest eradication campaigns, then the representatives committing government and industry funds to these campaigns need to be confident the pest diagnosis is accurate. In addition the laboratory making the determination needs to be sure it has followed a peer agreed test procedure and the staff undertaking those tests are competent.

For exotic diagnostic testing this is a particularly important consideration, as the laboratory would not be routinely running the test, and a false result could have significant implications to the industry or industries concerned. Any decision to commence an eradication program must be made on sound science.

In respect to laboratory accreditation in Australia, NATA has operated a quality assurance program for human pathology laboratories since 1987. The ISO has also developed an international laboratory standard. The international standard is designed to cover all types of testing laboratories including human, animal and plant diagnostic laboratories. While the NATA and ISO standards are sound in covering the general requirements for good laboratory practice and defining what a laboratory needs to do in order to meet these general requirements, they do not provide details on what is needed for a plant diagnostic laboratory. Each category of laboratory under the ISO/NATA system has their own specific set of requirements which overlay the general set of laboratory conditions to ensure "good laboratory practice" is achieved.

The use of the NATA or ISO standards has not been an issue in the past as in most cases those laboratories seeking accreditation in Australia have been medical laboratories, and the standard conditions set by NATA and ISO are well suited to these types of laboratories. The ISO/NATA general conditions have been overlayed by conditions set by the Therapeutic Goods Administration, and other sections of the Commonwealth Department of Health. Medical laboratories are heavily regulated and audited given the sensitivity of the tests they undertake and the funding sources involved, for example most funding is via the Commonwealth or state/territory governments.

More recently, AHA (PHA's animal equivalent) commenced an accreditation program for private veterinarians and is seeking to develop a national veterinary laboratory accreditation scheme. AHA is using NATA as the accrediting body and is using the NATA standards as a base for the accreditation scheme. In addition, they are also are developing specific animal diagnostic test standards. NATA audits the general ISO requirements and the industry specific standards. Some plant pathology laboratories in Australia are accredited with NATA, against the ISO laboratory standard, but there is no national, or international, plant pathology or entomology laboratory specific standard in existence.

In comparison to another plant based industry where test results are vital is the seed testing industry. In the international seed testing area there is an OECD seed scheme, an ISTA seed certification scheme and the US has its own NSHS.

These schemes all have the following characteristics:

- standards are developed for each diagnostic test and the tests have to be developed, tested and validated by an industry accreditation panel; and
- only accredited tests can be used for seed testing where international certificates are issued.

In addition, seed testing laboratories have to be accredited against the industry specific laboratory accreditation standards. Personnel in the laboratories are also audited against the industry test standards and laboratory standards. These audits involve detailed questions on the techniques used and determine what the technician understands the tests are for. By auditing to this level of detail the quality of the seed certification is recognised world wide. The same recognition cannot be said for the ISO accredited companies. Some ISO accredited companies have a very good reputation, while others do not have the same degree of recognition. For plant laboratories an accreditation system which is recognised in a positive way both nationally and internationally is required.

It is recommended that:

- an in house accreditation system be developed for plant diagnostics laboratories;
- the accreditation system uses the ISO quality system as a framework, as in the seed industry schemes; and
- the accreditation system is audited by technical experts.

What are some of the benefits of accreditation?

Another issue that needs to be considered is determining what benefits can be derived from an accreditation scheme. There are a number of benefits to be gained through the development and implementation of a plant diagnostic accreditation scheme.

These include:

- allowing the accredited laboratory to be confident that they are undertaking their tests accurately and against the appropriate peer agreed standard;
- providing opportunities for accredited organisations to market their professional competence; and
- providing decision makers with added confidence when making decisions on eradication programs.

For a laboratory which is operating in relative isolation from other similar facilities, accreditation provides an assurance that it is operating at an appropriate level within the industry. Many laboratories have also reported commercial advantages from being accredited.

Are all accreditation schemes equal?

The simple answer is no. To give an example, the ISO laboratory standard is a broad quality based system, which relies on the accredited laboratory determining the standards they will use and the level of qualification of staff amongst other things.

Accordingly, audits of this type of system can only measure compliance against the written manual of individual laboratories.

On the other hand, the seed testing schemes document the quality aspects of the system, as per the ISO approach, but the testing methodology used by all laboratories in the scheme and the qualifications of staff undertaking those tests are determined through internationally agreed technical standards. This type of accreditation allows for a greater degree of consistency in outcome between different laboratories throughout the world. The major difficulty with this approach can be achieving agreement on the technical standards to be used within the scheme. If a plant diagnostic accreditation system is to be developed in Australia, it is considered essential that a system based on the ISTA seed testing scheme be adopted. To this end PHA is working with diagnostic experts in Australia to develop a series of national diagnostic standards for exotic pests that have been identified through Industry Biosecurity Planning processes as being of concern to individual industries. These standards will be endorsed by a diagnostic steering committee and provide one of the three pillars for an Australian plant diagnostic accreditation scheme.

There are also differences in the auditing standards used to measure compliance with documented procedures. In the broader ISO arrangements, auditors on the whole, do not make detailed assessments on the validity of the test methods used or the competence of individual technicians within the laboratory. Audits of ISO systems generally ensure the company has documented testing standards and the company manual defines the competency standards required for their staff. They audit against these at a high level and do not drill down into the detail of specific tests, but only check that such tests exist and that the company being audited uses those tests and documents the results in accordance with procedure. There is no assessment on the merit of the test methods used, as long as they are based around generally accepted industry standards for the industry being assessed.

In a plant diagnostic sense, if one laboratory used an ELISA system and another used a PCR system for the detection of a plant pest, the ISO system would not assess if both tests were appropriate for the pest being targeted or identify any weaknesses in the different test methods. Diagnostic specialists working in exotic plant diagnostics will know how difficult it can be to get an overseas test working in an Australian environment. False negatives have been obtained in some cases where a test that worked overseas was used in Australia. The use of nationally agreed diagnostic standards alleviates this concern, however the auditing system needs to be robust enough to ensure the laboratory understands the limitations of any test being used. For this reason the more intense auditing arrangements, such as those used by the ISTA seed scheme, are more appropriate.

ISTA auditors will routinely observe technicians undertaking tests and measure their compliance with the externally set standards. In addition, the audit will assess the skills of the individual technicians running the tests. Often the audit includes having technicians run tests against known samples, and then comparing the results obtained with the correct answers.

This level of auditing does not mean the audit system needs to be more complex, as the benefit obtained by adopting industry agreed systems and standards is that the documentation and audit process for the individual laboratory is simpler. The auditing system adopted by the plant diagnostic scheme provides the second pillar in the plant diagnostic accreditation scheme.

The third and final pillar is the overall laboratory operating system. General hygiene (to avoid cross contamination between tests), occupational health and safety issues, and record keeping are but three parameters.

In this area the NATA and ISO standards provide all the detail needed for an Australian plant diagnostic accreditation scheme and it is recommended the appropriate aspects of those schemes be adopted.

Conclusions

The workshop participants recognised and endorsed the need for a plant diagnostic accreditation scheme to be established in Australia, and agreed that an accreditation system was needed to both support decision making and to ensure good laboratory practice was adopted by all laboratories involved in exotic plant pest identification.

The workshop also agreed that the accreditation system should not be overly complex and should not be excessively costly to gain and retain accreditation. Since the workshop, PHA has submitted a proposal to AFFA, seeking funding to develop a diagnostic network and to develop an accreditation scheme.

COMMENTARY BY WORKSHOP FACILITATOR

Professor Emeritus John Lovett

Professor Emeritus John Lovett is Managing Director of the Grains Research and Development Corporation (GRDC)

It is unusual to encounter a gathering of eighty professionals in any discipline where the degree of commitment to a common purpose was so strong as was evidenced at this workshop. The need for a diagnostic workshop is, plainly, very well recognised by professionals in the field.

While the initial focus of the workshop was on plant pathology, the strong opinion of those present was that the recommendations should be framed around a diagnostic network for pests. Further, that while the emphasis should be on exotic pests, endemic pest species should not be excluded. Implicitly, given the mandate of PHA (the workshop organiser), the focus of the discussion was on the establishment of an Australian diagnostics network.

In identifying the outcomes of the workshop several underlying elements can be defined as being critical to any attempt to achieve its objectives:

(a) Planning - the scope of the proposed diagnostic network and a timeframe for its establishment must be defined.

(b) Resources - the status of existing infrastructure, equipment and personnel requires validation. This will provide a starting point for appraising where critical mass is present, and where the potential for consolidation to achieve critical mass exists. Planning for the future, including succession planning for key personnel, will be imperative. Identifying the advantages of the network to potential supporters will be of paramount importance.

(c) Coordination - the means of coordinating and vitalising a network, once in place, must be determined.

(d) Accreditation - the development and maintenance, via appropriate quality control protocols, of accredited laboratories and personnel will be critical to the credibility of a network.

While the initial focus of a diagnostic network may, for reasons of logistics and resources, be Australia, the strong international contingent perceived an opportunity to establish, at least, an Australia/New Zealand axis and, in time, to develop a fully international network. The prospect of making more effective use of global resources is attractive and could be achieved, in large measure, through the development of communication linkages.

Resource constraints loomed large in the workshop discussions. Budget cuts are affecting, especially, public sector agencies worldwide. Sustaining a budget beyond the short term is challenging, research effort is fragmented and there is a lack of experience and awareness, especially in respect of new threats. There are some concerns regarding a lack of training to secure orderly succession for personnel.

Workshop participants were conscious that the use of services provided by a network will be determined by the unit cost of each service. While quality must not be compromised, the demand for each service is likely to determine its viability, especially in the commercial marketplace. In turn, this may limit the take-up of new technologies.

The likely constraints on a diagnostic network could pose severe risks to plant industries if, for example, the identification and impact of unfamiliar organisms and the possible use of some of these in bioterrorism was sub-optimal.

“Know your enemy” was, not surprisingly, a recurring theme. “Know your enemy - whatever the cost” is a challenge to be faced.

To address this challenge the development and maintenance of technologies which are sensitive, rapid, reliable, and user friendly is an imperative. Significantly, participants were firmly of the view that traditional techniques should be used alongside molecular approaches to diagnostics. The possibility of international collaboration to optimise resource use was recognised.

Nowhere is this approach more relevant than in the context of containment laboratories. In the Australian context, workshop participants compared the merits of having access to onshore facilities, where the need

for ultra-high security is a significant limitation on activities, with the advantages of working offshore in existing facilities, and without such severe restrictions on the work that can be carried out. There are a number of examples of effective collaboration between Australia and New Zealand in this regard.

While the attractions of international and national activities are recognised, a strong view was put to the workshop that skilled diagnostics practitioners must be maintained in, for example, regional Australia. Resourcing regional laboratories as a diagnostics "front line", with recourse to more sophisticated range of technologies, combining the best of traditional with molecular approaches, at a small number of "centres of excellence", is an option that should be investigated.

The capacity of the existing human resource to meet diagnostic needs is in question. A view that, for all techniques, there is a shortfall in training and consequently a lack of experience and practical expertise was put to the workshop. Accredited training of personnel to achieve best practice, in accredited laboratories with independent monitoring of adherence to protocols, is essential to underpinning a diagnostic network.

Linking researchers to diagnostics practitioners to promote early detection of pest problems was recognised as a priority. "Early detection for later action" was endorsed as a guiding principle. The point was made that the assertion "That pest is not here" may, in fact, mean "That pest has not yet been identified here". The need to secure and enhance taxonomic collections to underpin identification is a major challenge. It was noted that a comprehensive collection need not, necessarily, exist at a single location.

Taxonomic collections have not rated highly in competing for scarce research and development investment. The same may be true of many of the technologies of diagnostics.

"Know your customer" was advanced as a guiding principle in the quest to secure a resource base. Competition for the contents of the public purse, from sectors such as health, education, and law and order will only be countered by persuasive argument in favour of the positive outcomes from a diagnostics network. Maintaining biosecurity, and biodiversity, are among these arguments.

From the views expressed as this workshop, a fully effective, comprehensive diagnostics network is most likely to result from broad, international collaboration. Some elements already exist. New Zealand, for example, supports a reference laboratory (the National Plant Pest Reference Laboratory). Industry funds support diagnostic services and revenue is raised through pest management consultancies. Some commercial activity may be anticipated in an effective diagnostics network. This may be a means of attracting private sector investment into such a network, but the absence of private sector representation at the workshop suggested, likely, limited interest.

In Australia, the involvement of the CRC for Tropical Plant Protection in the development of the Northern Australian Diagnostics Network is an initiative that should be examined as a contribution to developing a platform for a more comprehensive Australian approach to diagnostics.

As a broader example of initiatives already extant, the databases of CAB International were recognised as a relevant contribution to developing international linkages. It may be noted that CAB International has successfully brokered a very broad base of support for its Crop Protection Compendium, which is recognised as a landmark international contribution.

To a significant extent, certainly in terms of meeting information needs, a "virtual" diagnostics network, using the best means of electronic data handling and communications, can be envisaged. The development and maintenance of such a network would, of course, require just as rigorous a regimen of governance as would, say, laboratories at a national or regional level.

The initiative of PHA in mounting the workshop, in conjunction with the 8th International Congress of Plant Pathology, was appreciated. The endorsement by the PHA Board of the recommendations of Moran and Muirhead (2002) was noted. Accordingly, PHA was identified as the entity most likely to carry forward the recommendations of the workshop to a successful conclusion.

WORKSHOP RECOMMENDATIONS

The workshop agreed that the following recommendations should be submitted to the Board of PHA for consideration.

The PHA/ICPP Workshop on 'Developing a world class plant diagnostic workshop' recommends:

- the development of a cost effective diagnostic network for pests that will, in the first instance, be developed in Australia. This will be a two stage process involving:
  (1) enhancing the networking capacity of existing laboratories
  (2) identifying centres with specific capabilities, including biosecurity, and securing their national roles and responsibilities
- the establishment and introduction of an accreditation system for laboratories and personnel, and the development of a series of standardised protocols (using the most appropriate technology).

ABOUT THE WORKSHOP SPEAKERS

Professor Emeritus John Lovett facilitated the workshop and is Managing Director of the GRDC. Formerly Professor of Agronomy at the University of New England, Professor Lovett has wide experience in science, technology, communications, environmental matters and the management of research and development. He is a former Chairman of the Oilseeds Research Council, and became Deputy Chairman of the inaugural GRDC Board in October 1990.

Mr Andrew Inglis AM was appointed as Chairman of PHA in early 2000, and has extensive experience serving on national and international agriculture-related industry and government bodies, especially in relation to grains research and production. Mr Inglis was a member of the 1996 Nairn Review of Australian quarantine, and is Chairman of the CSIRO Entomology Advisory Committee, Deputy Chairman of the Quarantine and Exports Advisory Council, and also sits on the Board of the CRC for Weed Management.

Dr Bill Roberts is the Chief Plant Protection Officer with Agriculture, Fisheries and Forestry - Australia (AFFA), and has previously held research and teaching positions at a number of universities and research institutes both in Australia and overseas. Dr Roberts has extensive experience with quarantine systems and international standards developed under the International Plant Protection Convention (IPPC), and has been involved with expert working groups developing standards for risk analysis, the revision of the IPPC, and on Genetically Modified Organisms and environmental risks.

Dr Laurene Levy is the Director of the Plant Germplasm Quarantine and Biotechnology Laboratory that is within the APHIS-PPQ, Centre for Plant Health Science and Technology. Her area of expertise is the development of molecular biological and serological detection and characterisation strategies for plant pathogens, especially plant viruses and viroids.

Dr Levy received her PhD in Plant Pathology from the University of California where her research focus was the purification, characterisation, and detection of citrus viruses. Over the past 12 years she has worked at the USDA on the serological and molecular biological detection technologies, and characterisation of PPV and other quarantine pathogens.

Dr John Elphinstone is a bacteriologist working within the CSL Plant Health Group, as a member of the Plant and Environmental Bacteriology Team. Dr Elphinstone has been with the CSL for nine years, and his expertise covers the epidemiology, ecology and integrated management of plant pathogenic bacteria and the serological and molecular detection and identification of bacterial plant pathogens. He is a member of the Editorial Board of Plant Pathology and an author of more than 30 scientific reports and papers on plant pathogenic bacteria.

Dr Suzy Bentley is a Senior Research Officer with the CRC for Tropical Plant Protection. Dr Bentley's training is primarily in molecular biology, and her major research interests include genetic characterisation and detection of fusarium wilt diseases, particularly fusarium wilt of banana and cotton, for which the CRC for Tropical Plant Protection has developed DNA based diagnostic tests.

Professor Denis McGee is a Professor of Plant Pathology at Iowa State University, and has a Bachelor of Science in Botany and a doctorate in Plant Pathology. Denis has held research positions in government agencies and universities in Australia, Canada, and the United States, and has extensive expertise in Seed Pathology and Epidemiology of Plant Diseases.

Dr Richard Sheldrake is Director General of NSW Agriculture and Chief Executive of the NSW Rural Assistance Authority. Dr Sheldrake has a strong veterinary research background, and undertook his PhD studies in the Faculty of Medicine at the University of Newcastle, where he examined basic mucosal immune mechanisms of the mammary glands of sheep. Within NSW Agriculture, he has held a variety of positions, including Director (Animal Production, Research), Deputy Chief (Division of Animal Production), Program Manager (Dairy and Intensive Livestock), Chief, (Division of Corporate Services), Executive Director, (Research, Advisory & Education) and Director, (Animal Welfare Unit). Dr Sheldrake has also been the recipient of a Churchill Fellowship to the US, where he examined ways to better manage research, development, and extension.

Dr Margaret Williams is Manager of Diagnostic Services for DPIWE, and previously held the position of Principal Quarantine Entomologist. In her current role, Dr Williams has responsibility for diagnostic laboratories in the areas of plant health (entomology and plant pathology), animal, and fish health and seed analytical services, amongst others. A plant health laboratory and the animal health laboratory under her management are accredited to ISO 17025 and the seeds laboratory is accredited through ISTA.

Mr Rodney Turner is a Program Manager with PHA, and prior to this, spent 20 years working in both operational and policy areas with AQIS. During this time, Mr Turner worked in import and export areas for both grain and horticulture, and developed QA procedures for AQIS's import and export plant quarantine areas. In addition, Mr Turner has been involved in the development of a number of international quarantine standards.

WORKSHOP PARTICIPANTS

Facilitator:

Professor John Lovett	Grains Research and Development Corporation, Australia

PHA representatives:

Mr Andrew Inglis	Chairman, Plant Health Australia
Mr Neil Fisher	CEO, Board Director, Plant Health Australia
Mr Brian Newman	Board Director, Plant Health Australia
Mr Rodney Turner	Program Manager, Plant Health Australia (Speaker)
Dr Simon McKirdy	Program Manager, Plant Health Australia
Mr Garth Donovan	Communications Officer, Plant Health Australia
Ms Suzie Patrick	EA/Office Manager; Minute Secretary, Plant Health Australia
Miss Catherine Quinn	Secretary/Receptionist, Plant Health Australia

In attendance:

Dr Suzy Bentley	Australia (Speaker)
Dr John Elphinstone	United Kingdom (Speaker)
Dr Laurene Levy	United States of America (Speaker)
Dr Denis McGee	United States of America (Speaker)
Dr Bill Roberts	Australia (Speaker)
Dr Richard Sheldrake	Australia (Speaker)
Dr Barney Stephenson	New Zealand (Speaker)
Dr Margaret Williams	Australia (Speaker)
Dr Brett Alexander	New Zealand
Dr Stephen Allen	Australia
Dr Dominik Begerow	Germany
Dr Neale Bougher	Australia
Mr Mark Braithwaite	New Zealand
Dr Angus Carnegie	Australia
Dr Ron Close	New Zealand
Dr Gerard Clover	New Zealand
Dr John Curran	Australia
Mrs Jenny Davidson	Australia
Mr Richard Davis	Fiji
Dr André Drenth	Australia
Ms Kim Eade	New Zealand
Dr Jacqueline Edwards	Australia
Mr David Elliott	New Zealand
Mr John Fletcher	New Zealand
Dr Rob Floyd	Australia
Dr Angela Freeman	Australia

Mr Stojan Ganev	New Zealand
Mr George Gill	New Zealand
Dr Chin Gouk	Australia
Mr Nik Grbavac	New Zealand
Mrs Barbara Hall	Australia
Lindsay Hawke	New Zealand
Dr Juliane Henderson	Australia
Dr Veronica Herrera	New Zealand
Dr Mark Holderness	United Kingdom
Mr Mark Holland	Australia
Mr Ian Hood	New Zealand
Mary Horner	New Zealand
Mr Kelvin Hughes	United Kingdom
Ms Sarah Jacobson	Australia
Dr Om Jhorar	Australia
Prof Michael Jones	Australia
Dr Roger Jones	Australia
Dr Wadia Kandula	New Zealand
Dr Lawrence Kenyon	United Kingdom
Dr Stephen Langrell	Australia
Dr Benedicte Lebas	New Zealand
Dr Peter Long	New Zealand
Dr Jo Luck	Australia
Mr John Marshall	New Zealand
Dr Vessela Mavrodieva	United States of America
Dr Peter Merriman	Australia
Dr Caroline Mohammed	Australia
Dr Jane Moran	Australia
Dr Louise Morin	Australia
Dr Gordon Murray	Australia
Dr David Nehl	Australia
Dr Francisco Ochoa-Corona	New Zealand
Dr Kathy Ophel Keller	Australia
Ms Julie Pattemore	Australia
Dr Jacek Plazinski	Australia
Prof Terence Price	Papua New Guinea
Dr Geoff Ridley	New Zealand
Dr Brendan Rodoni	Australia
Dr Vera Sergeeva	Australia
Norman Schaad	United States of America

Dr John Sherwood	United States of America
Miss Tamsin Smales	New Zealand
Dr Merrin Spackman	Australia
Dr Peter Stephens	Australia
Dr Brett Summerell	Australia
Mr Eli Szandala	Australia
Mr Robert Taylor	New Zealand
Len Tesoriero	Australia
Dr Vivien Vanstone	Australia
Mr Tim Wardlaw	Australia
Mr Matthew Weinert	Australia
Mr Mark Whattam	Australia
Dr Joanne Wilson	New Zealand
Dr Jacqueline Wright	Fiji

GLOSSARY

AAHL	Australian Animal Health Laboratory
AFFA	Agriculture, Fisheries and Forestry - Australia
AHA	Animal Health Australia
AHC	Animal Health Committee
APHIS	Animal and Plant Health Inspection Service - United States
AQIS	Australian Quarantine and Inspection Service
BSE	Bovine Spongiform Encephalopathy
CRC	Cooperative Research Centre
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CSL	Central Science Laboratory - United Kingdom
DEFRA	Department for Environment, Food and Rural Affairs - United Kingdom
DHS	Department of Homeland Security - United States
DNA	Deoxyribose Nucleic Acid
DPIWE	Department of Primary Industries, Water and Environment - Tasmania
ELISA	enzyme linked immunosorbent assay
EMAI	Elizabeth Macarthur Agricultural Institute
EU	European Union
FMD	Foot and Mouth Disease
GDP	Gross Domestic Product
GRDC	Grains Research and Development Corporation
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ISTA	International Seed Testing Association
NAPIS	National Agricultural Pest Information System - United States
NATA	National Association of Testing Authorities
NIS	National Inspection Service - United States
NP2D2N	National Plant Disease and Pest Diagnostic Network - United States
NSHS	National Seed Health System
NSW	New South Wales
OECD	Organisation for Economic Cooperation and Development
OIE	Office International Des Epizooties
PCR	Polymerase Chain Reaction
PHA	Plant Health Australia
PPV	Plum Pox Virus
PVX	Potato Virus X
PVY	Potato Virus Y
QA	quality assurance
TAFE	Technical and Further Education
UK	United Kingdom
US	United States
USDA	United States Department of Agriculture

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