



CONTENTS

- 2 Air Transport of Specimens – Latest News

- 2 National Aquatic Animal Health Technical Working Group

- 2 AusAVLD Inaugural Meeting

- 3 Pathology Standards

- 3 ANZSDPs

- 3 Specimen Packing and Air Transport

- 3 ANQAP

- 4 Measurement of Uncertainty in veterinary diagnostic testing

- 4 Changes to SCAHLS New Test Approvals

- 5 Australian Biosecurity Cooperative Research Centre invests in research and education and training in the biosecurity area

- 5 Australian Reference Laboratories

NEW BIOSAFETY/BIOSECURITY Regulations Planned

At our recent SCAHLS meeting in Darwin we considered the management of infectious pathogens in research and diagnostic laboratories and some of the proposed changes being implemented by the Department of Health and Ageing.

During the past 20 years the focus has been on managing infectious pathogens from aspects of bio-safety, and to a lesser extent, bio-security. Most of these issues have been dealt with through Occupational, Health and Safety regulation and practices. More recently the genetic alteration of microbes has led to a series of regulations laid down by the Office of the Gene Technology Regulator (OGTR)

Events surrounding September 11th, and in particular the anthrax attacks, have profoundly changed things. The United States has identified a set of agents (pathogenic organisms and related compounds) which require a strict set of processes and procedures to be undertaken by anyone wishing to handle them.

The Department of Health and Ageing (DOHA) is now addressing the management of infectious agents held for research or diagnosis. A series of workshops were held around Australia in late 2004 to examine the creation of rules to manage both the bio-security/bio-terrorism, and the bio-safety aspects.

These meetings resulted in a set of proposals based around:

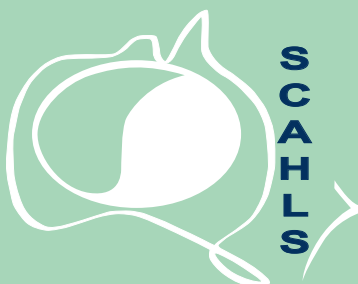
- A list of agents that would fall under the rules
- Procedures for those working with listed agents

- Compliance monitoring

Initially, three groups of agents were created. Group A consisted of 6 – 10 pathogens with a high bio-security (bio-terrorism) potential. Group B was split into two. The first comprised those agents with significant bio-terrorism potential and high bio-safety requirements. The second listed agents with relatively low bio-terrorism potential but a significant bio-safety potential. Group C included agents with negligible bio-terrorism potential but some bio-safety issues.

In each case, a set of procedures was devised to best manage the risks associated with institutes holding or handling such agents. These focused on the physical aspects of the areas in which the agents were held or used, an audit trail and requirements for personnel working with the agents (e.g. security checks). Clearly, the extent and cost of the procedures were highest for those agents in Group A, lower for Group B and least for Group C.

It now seems that DOHA has finalized the process but the list, the rules governing the select agents on the list and the compliance monitoring body remain confidential. What is clear is that these new regulations will have significant repercussions for all of us working in veterinary laboratories. There will need to be changes to the way we do things, changes in what we are allowed to handle and, perhaps most crucially, costs involved especially for those with PC3 and PC4 laboratories. This is a “space” worth watching in the coming months.



Air Transport of Specimens – Latest News

IATA (International Air Transport Association) issued an Addendum II to its Dangerous Goods Regulations 46th edition, on 22 March 2005, effective immediately.

The good news is that fewer infectious substances are now classified under Category A as infectious substances affecting humans, UN number 2814, or infectious substances affecting animals, UN number 2900, unless they are cultures. African horse sickness virus and bluetongue virus have been removed from UN 2900 altogether and all others on that list can be sent as Category B infectious substances unless they are cultures. In addition, the definition of culture has been amended and while previously all cultures had to be sent as Category A infectious substances, cultures of organisms of “low pathogenicity” can now be classified as Category B infectious substances.

Category A is defined as: “An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals”. Category A infectious substances must comply with Packing Instruction 602 and must be accompanied by a Shipper’s Declaration.

Category B infectious substances are those that do not meet the criteria for inclusion in Category A. These infectious substances must be assigned to UN number 3373 and must comply with Packing Instruction 650 (pp 454 & 455, IATA DGR 46th edition) but do not need a Shipper’s Declaration. Most veterinary infectious diagnostic specimens now fall under category B.

Addendum II reads: “*The proper shipping name of UN 3373 is **Diagnostic specimens, Clinical specimens or Biological substance, category B.** On January 2007, it is anticipated that the use of the shipping names *Diagnostic specimens and Clinical specimens* will no longer be permitted.*”

Within Australia, the CASA (Civil Aviation Safety Authority) requirement that all commercial shippers of dangerous goods (including UN3373) must be trained, has been in force since 1 July 2004.

AusAVLD Inaugural Meeting

The purpose of Australian Association of Veterinary Laboratory Diagnosticians is to provide all staff in veterinary laboratories with a forum to exchange information and to facilitate continuing education. The vision is that the Association will be modelled on the very successful American Association of Veterinary Laboratory Diagnosticians. Responses to a survey of laboratory staff have indicated that there is sufficient interest to warrant holding an inaugural meeting. The response to this meeting will determine the viability or otherwise of the idea.

A SCAHLS workshop and meeting in September is expected to attract some prospective AusAVLD members to Melbourne. An organizing committee is therefore developing a program for the inaugural AusAVLD meeting to be held on Thursday and Friday (22-23 September) following the SCAHLS workshop at Attwood, Victoria. Interested people should contact Peter Kirkland (02 4640 6331) or Jan Beattie (03 9217 4200) with ideas for the program. All respondents to the survey will also be contacted directly. The committee would be especially keen to hear from people wishing to present a paper that will be of interest to the multidisciplinary audience. A glance at the program for the AAVLD meeting in November 2005 might help stimulate some ideas (http://www.aavld.org/aavld-3/annual_meeting2.jsp).

National Aquatic Animal Health Technical Working Group

The National Aquatic Animal Health Technical Working Group (NAAH-TWG) is a committee with a similar role to SCAHLS. NAAH-TWG provides scientific and technical advice to the Aquatic Animal Health Committee (AAHC). It provides a technical forum at which aquatic health issues can be discussed between States and the Commonwealth and provides a network for harmonizing the activities of, and promoting information exchange among, professionals in Federal, State and industry sectors.

It also provides policy background papers for AAHC, facilitates and organises protocols and standards for aquatic animal health diagnostic activities in consultation with SCAHLS and the Australian National Quality Assurance program. NAAH-TWG meet once a year and have recently employed Jill Birrell as their Executive Officer.

Pathology Standards

The Australian Animal Pathology Standards Program (AAPSP) is now in operation with activities to occur across a range of topics in 2005. The management committee includes Tony Ross (scientific coordinator), and Keith Walker (host institution), Roger Kelly (ASVP), and Barry Richards (SCAHLs) and Mike Bond Animal Health Australia (chairman).

The histopathology proficiency testing program has started, with glass slides distributed. The first round was completed at the end of April. This involved an assessment of the technical quality of the stains applied, and the pathological interpretation of lesions present. Evaluation of interpretations is based on a laboratory response rather than an individual pathologist response. Three more rounds are planned for 2005.

The continuing professional development program got under way during May, with presentations this year being delivered by Professor Fabio del Piero of the University of Pennsylvania, USA, who is in Australia with the assistance of the Charles Louis Davis Foundation. The topic was gastrointestinal pathology of ruminants, pigs, horses, chickens, fish and small animals. Prof del Piero delivered 2-day workshops in each of the mainland capital cities with Tasmanian pathologists assisted to attend the Melbourne course. The inaugural 2005 series was registration-free for all interested pathologists. From 2006, attendance at these courses will require AAPSP membership (for laboratory-based pathologists) or a registration fee (for free-lance pathologists and other interested veterinarians).

Other activities include digitisation of the information in the now superseded National Registry of Domestic Animal Pathology (NRDAP), upgrading of the histopathology slide collection

(with generous assistance from AFFA), development of a AAPSP web-page using the AHA website, development of a second opinion service and further work on education modules for pathology trainees.

ANZSDPs

The new ANZSDP for Porcine Circovirus Infection (PCV) was published on the SCAHLs web-site in December 2004. Several more ANZSDPs are nearing the publication date. They include: Hendra Virus Disease, Enzootic Bovine Leucosis, Bovine Pestivirus, Bovine TB and Virulent Avian Influenza. The current list of ASDTs has been re-examined and a number of these documents will be revised, with ANZSDPs to be written over the next 6 months. These include: Newcastle Disease, Akabane Disease, Bluetongue, Infectious Bovine Rhinotracheitis, Bovine Ephemeral Fever, Caprine Arthritis–Encephalitis, Equine Infectious Anaemia, *Elaphostrongylus* in Deer, Equine Babesiosis, Tick-Borne Diseases in Cattle and Toxoplasmosis.

ANQAP

Duplicate Tests for 2005.

There are a number of additions to duplicate testing for the program in 2005. Duplicate tests are: NDV HI, Avian Influenza AGID, JD ELISA, JD CFT, JD (ov) AGID, Aino VNT, Akabane VNT.

ANQAP also requires serum for the following tests:

Chlamydia CFT positive (ovine or bovine), EBL serum and milk –positive, *Ovine brucellosis* CFT and ELISA positive, Q fever CFT positive (ovine or bovine), *Leptospira pomona*, hardjo and (particularly short of) tarassovi positives, JD CFT and ELISA positive serum, Ovine JD AGID (1+ very short), BVD positive whole blood for BVD Ag ELISA and BVD non-cytopathic serum for virus isolation. Please help out if you can.

Specimen Packing and Air Transport

Australian Civil Aviation regulations that came in to force on 1 Jan 2005 require packaging, to IATA Packing Instruction 650, of all specimens designated 'dangerous goods', which includes known infectious substances and most diagnostic specimens. Since IATA training is required for this task, it creates problems for those sending specimens from remote locations in Australia. However, when sending diagnostic specimens by air to a laboratory, all submitters must not only pack the specimens correctly, but must have completed the training course. Guidelines (for IATA packing instruction 650) are available on the IATA website (<http://www.iata.org>) and packing courses can be done on-line. It is incumbent upon laboratories to make their clients aware of this requirement, and the training options, since there are substantial penalties for non-compliance.

These regulations are in a state of flux as CASA attempts to meet international guidelines (which are themselves constantly changing). Despite repeated assertions that the matter is at the point of resolution (now said to be April 2005), it is likely that further debate will occur. There is a possibility that the packing requirements for all diagnostic specimens (air and ground travel) will be standardised, with even further implications for Australian veterinary laboratories.

Measurement of Uncertainty in veterinary diagnostic testing

SCAHLs has established a working group to examine MU in veterinary testing. The first draft of a consensus paper was discussed at the SCAHLs meeting in March.

In summary, there was consensus about the following:

1. Measurement of uncertainty cannot be estimated in veterinary testing in a strict metrological sense.

Whereas the estimation of MU can be readily performed for such methods as measuring the concentration of chemical substances of low molecular weight, the situation in a veterinary laboratory testing for disease diagnosis is quite different. The underlying principle in such test methods is that the relative activity of specific antibodies or antigens, for example, is determined rather than the concentration of these macromolecules.

2. Uncertainty in veterinary testing is expressed through proper assay validation

As stated by the OIE Manual 2005; "A validated assay consistently provides results that identify animals as positive or negative for an analyte or process (antibody, antigen, or induration at skin test site) and, by inference, accurately predicts the infection status of animals with a predetermined degree of statistical certainty".

The overall estimate for MU is precision. Repeatability and reproducibility are measurements of precision available through continuous monitoring of internal quality control data.

Reproducibility estimates are available through participation in external proficiency test programs such as ANQAP.

This principle provides an overall measurement of precision. It does

not include the uncertainty of individual steps during the diagnostic process or take into account pre- and post-analytical sources of error, e.g. sampling, transcript, transformation errors, etc. It would be expected then that all laboratories should have adequate procedures for method validation and that these include estimates of uncertainty.

3. Uncertainty data should not be provided routinely in client report letters

MU is a critical part of method validation and is valuable data to be taken into consideration by the laboratory scientist when reporting the results and by the veterinarian when making the diagnosis, but is deemed of little value (and probably confusing and misleading) to the client. Since veterinary testing allows interpretation of results, which are reported to the client, the consideration of MU has already been made and no further consideration would be of significant value.

4. Examples for MU in diagnostic testing

It was agreed that it will be useful to have worked examples for MU in veterinary testing for different areas e.g. haematology, immunology, parasitology, bacteriology, mycology, biochemistry etc. At this stage, examples and useful information can be found at

http://www.oie.int/eng/normes/mmanual/A_00012.htm (OIE manual of diagnostic tests and vaccines for terrestrial animals (2004) Chapter I.1.2. Quality management in veterinary testing laboratories 6d) Test methods - Uncertainty. Office International des Epizooties (OIE), 12 rue de Prony, 75017, Paris, France, p. 18)

NATA news March 2005, Issue 115 gives several examples of how to apply MU in medical testing. Some of these are available at: <http://www.rcpa.edu.au/applications/DocumentLibraryManager2/upload/Uncertainty%20of%20measurement.pdf> and http://www.allergy.org.au/pospapers/Uncertainty_of_Measurement.htm

Changes to SCAHLs New Test Approvals

SCAHLs approval of new diagnostic tests that will ultimately be included in ANZSDP's is to be managed using a new process. Applicants will be asked to fill out one of two templates that were developed during 2004-2005. The template to be used for nucleic acid based tests has been finalised and is now being used. The template for serology tests is in draft form and although it will be improved over 2005 it is available for new serology test approval applications.

These templates were developed in response to OIE changes for their new test approvals, and we believe integrate the OIE requirements into a simpler format. All new tests need to state the purpose of the test and provide acceptable validation. Applications will be assessed by the New Test Development Working Group (Deb Cousins Chair, Russell Rogers, Axel Colling) and will be referred to other external experts for review as appropriate.

Requests for the appropriate template should be directed to the SCAHLs Executive Officer Andrew Gregory (agregory@agric.wa.gov.au), who will record the application and forward to the New Test Development Working Group for evaluation and feedback.

Australian Biosecurity Cooperative Research Centre invests in research and education and training in the biosecurity area

The Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease (AB-CRC) was established in November 2003. Its aim is to protect Australia's public health, livestock, wildlife and economic resources through research and education that strengthens the national capability to detect, diagnose, identify, monitor, assess, predict and respond to emerging infectious disease threats which impact on national and regional biosecurity.

The objectives of the AB-CRC are to:

1. Develop more cost-effective tools and systems for disease detection and surveillance, and to expand our knowledge of the potential for emerging infectious disease threats to establish and spread within Australia.
2. Transfer knowledge and technologies to the livestock, public health, environment and community sectors by enhancing national and international collaborative linkages and networks across research, government and industry sectors, contributing to more effective surveillance and response systems within Australia and the Asia-Pacific region.
3. Equip researchers, professionals and members of the community within Australia and the Asia-Pacific region with appropriate knowledge and skills for responding to emerging infectious disease threats, in accordance with community and industry needs and expectations.
4. Exploit the commercial potential of tools and systems for disease detection and surveillance, and education and training products.

The AB-CRC currently supports 20 PhD students and 17 research projects. Training will be delivered through short courses and Masters programs, and a summer school is planned for February 2006. All states and territories apart from South Australia and Tasmania are currently involved in AB-CRC research programs.

The success of national benefit cooperative research centres such as the AB-CRC relies on delivering measurable outcomes from its research and education programs. The AB-CRC's Application & Linkage Program is the key mechanism for maximising the success of the AB-CRC's Research Program and Education & Training Program by ensuring that they translate into real changes in both policy and practice in the biosecurity arena.

For more information about the AB-CRC visit www.abcrc.org.au or email info@abcrc.org.au

Australian Reference Laboratories

- Johne's Disease Reference Laboratory, (Victorian Institute of Animal Science)*
- Australian Reference Laboratory for Bovine Tuberculosis, (Department of Agriculture, Perth)*
- Footrot Reference Laboratory, (Department of Agriculture, Albany)
- Anthrax Reference Laboratory, (Elizabeth Macarthur Agricultural Institute, NSW)
- Newcastle Disease Reference Laboratory (Australian Animal Health laboratory, Geelong)*
- Avian Influenza Reference Laboratory (Australian Animal Health Laboratory, Geelong)*
- Bluetongue Reference Laboratory, (Australian Animal Health Laboratory, Geelong)*
- Hendra and Nipah Virus Disease Reference Laboratory, (Australian Animal Health Laboratory, Geelong)*
- Rabies Reference Laboratory, (Australian Animal Health Laboratory, Geelong)*
- Brucellosis Reference Laboratory, (Australian Animal Health Laboratory, Geelong)*

*Note: *Also OIE Reference Laboratories*