Strengthening biosafety linkages and collaborations between Australia & New Zealand"

ISSUE 1
May 2019

Newsletter

Hello and welcome to 2019. I am feeling a sense of Deja-vu as I am sitting in a Wellington Airport waiting to fly back to Australia following an excellent meeting of the International Veterinary Biosafety Working group.

To be able to speak with and learn from the worlds brightest, most passionate and extremely engaged large animal professionals was truly amazing. It also got me thinking how well prepared are we? Each of these member countries have at some point in time had to deal with animal pandemics on a staggering magnitude.

We learned about the responses, the strain that it puts on the entire supply chain from field workers taking samples, to laboratories needing to process pandemic quantities of samples, to limited supplies of earth working equipment to move and dispose of huge volumes of waste, to roads and areas and livelihoods being put on hold or in some cases completely lost, to the supply chain not being able to cope with even basic necessities such as plastic tubs and PPE.

The conference reinforced to me that Australia and New Zealnd are in a truly unique global position and in a position that we should fiercely protect for the future of our economy and that of future generations. I was also heartened to see that our facilities are not that dissimilar to those around the world. Its also heartening to be part of a community of individuals and companies who are so passionate about education and knowledge sharing for the benefit of our planet.

2019 seems to be the year of Standard update ABSANZ has been invited to collate member response to a number of important standards that are relevant to our industry. This edition of the newsletter contains the relevant information on how members can contribute – most submissions are due end of May so don't miss out.

Stephen Coulter
Editor

In this issue

STANDARDS ONLINE

If you are interested in becoming a regular contributor to the released drafted Australian and New Zealand standards. Please check the following:

https://sapc.standards.org.au/sapc/public/listOpenCommentingPublication.action

There are no alert systems as part of the Standards on line system hence you will need to regularly check if there are standards that might impact your work.

Relevant AS/NZS Standards for review and comment

Over the past three months there have been public consultation for the following standards

- AS2243.1 Safety in Laboratories Planning and Operational Aspects – Comments closed Jan 2019
- AS2243.2 Safety in Laboratories Chemical Aspects – Comments Closed Jan 2019
- AS2243.3 Safety in Laboratories Microbiological Aspects – Comments Closing 30 May 2019

ABSANZ joint submission to AS2243.3 Safety in Laboratories AS/NZS 2243, part 3 – Microbiological safety and containment.

DR 2243.3:2019 is now available for a second round of comments. This round of public consultation will run through to the end of May 2019.

Key amendments that have been made to the standard include:

The addition of:

- Section 9 - Aquatic organism containment
- Appendix H – Safe use of Class I and II Biological Safety Cabinets (retaining key information from AS2647)
- A complete rewrite of Appendix B covering the containment requirements for poliovirus

Changes to:

- **Section 2**: Organization and responsibility, particularly regarding risk assessment
- Plant infectious microorganism risk categorisation (RG4 and corresponding requirement for PC4 now removed)
- **Section 3**: Indicative risk group tables providing example microorganisms
- **Section 5**: Laboratory containment facilities (clarity regarding required safe work practices are worth noting in particular)
- **Section 11**: Chemical, PPE and special equipment
- **Section 13**: Contaminated materials and waste

If you would like to have your comments included in an ABSANZ submission, please email these through to execofficer@absanz.org.au using the comments template by COB **Friday 17 May.**

These will then be compiled and submitted to Standards Australia on your behalf. Please note that comments not provided using the template will not be accepted. (SIA Global template is very specific in the way data must be entered – please ensure you allow enough time to enter comments into the templates).

ABSANZ joint submission on the draft of the 4th Edition of the WHO Laboratory Biosafety Manual

The WHO Laboratory Biosafety Manual (LBM) seeks since its first edition published in 1983 to improve biosafety for laboratory activities. Now nearing the completion of the fourth edition of the LBM, we are looking for feedback from a broader group of institutions.

The LBM consists of a core document and supplementary seven monographs, deepening and exemplifying the evidence- and risk -based approach for biosafety being introduced in the LBM4.

This manual should complement national regulations and oversight mechanisms that may be in place, and be used to assess, control and review risks at the local or institutional level. Additionally, it will supplement or provide new insights and best practices for consideration.

The core document covers the following areas:

- risk assessment, control and review
- core requirements for biosafety
- options for heightened control measures
- maximum containment measures for very high-risk operations
- transfer and transportation of infectious substances
- biosafety programme management
- laboratory biosecurity
- national and international biosafety oversight

For the reviewing process, we would like to have your feedback about the core document. The monographs provide more detailed information and help to implement systems and strategies on specific topics.

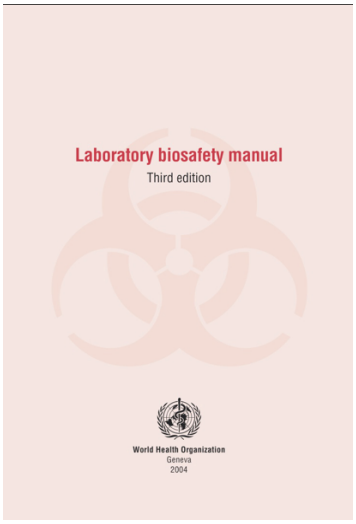
The monographs include:

- Risk Assessment
- Biosafety Programme Management
- Laboratory Design and Maintenance
- Personal Protective Equipment
- Biological Safety Cabinets and other Primary Containment Devices
- Decontamination and Waste Management
- Outbreak Response

The above-mentioned risk -based approach is proposed in lieu of the risk group classification of biological agents and biosafety levels as found in the 3rd edition of the LBM, enabling the laboratories to adopt tailored solutions for enhanced biosafety with maximum flexibility which is beneficial particularly but not limited to resource-limited countries.

ABSANZ members have an opportunity to provide comment on the fourth edition of the WHO Laboratory Biosafety Manual. Feedback provided will inform a collective summary narrative from ABSANZ to be included in a collated response to WHO from the International Federation of Biosafety Associations (IFBA). A copy of the draft Edition hyperlink is provided on the ABSANZ website

Comments should be provided by email to execofficer@absanz.org.au by COB Friday 17 May. These will then be reviewed and incorporated into a summary submission to be provided to IFBA to collate for a collective response to the WHO. Please refer to the information below to guide your comments:



Department of Agriculture and Water Resources

Revised BC2 Criteria

Department of Agriculture and Water Resources will be releasing the latest BC2 standards later this year. The biggest change will be for our plant facilities which will in most cases no longer require 250um screening in liquid waste streams under specific circumstances. We will let ABSANZ members know when the revised criteria is available.

Bovine Serum

From 2nd April 2019 the department of Agriculture have made changes to the way that bovine serum is imported into Australia. Full details of the process can be found on the ABSANZ website. Key points as follows;

The changes relate to the importation of bovine serum (including foetal bovine serum and new born calf serum) and plasma, in volumes greater than 20ml or 20g per individually packaged unit for in-vitro or in-vivo in laboratory animals end use;

Changes are not being made to the following:

- By-products of bovine serum or plasma are excluded, e.g. bovine serum albumin, antibodies derived from bovine serum.
- Bovine serum or plasma that is sourced, manu factured and exported from New Zealand.

Changes

The assessment of permit applications for bovine serum and plasma (including foetal bovine serum and new born calf serum), in volumes greater than 20ml or 20g, will focus on the product supply chain, disease freedom and cross contamination controls.

The following information will be required to be provided in support of import permit applications:

Details regarding the importer in Australia

- Details regarding the overseas manufacturer
- Details of the supply chain including the exporter in the country in which the goods are loaded for transport to Australia
- Countries of origin, residence and slaughter for the source animals
- Details of all supply chain steps (including: abattoirs, donor farms, primary/secondary/final processing plants, QC testing laboratories, stor age warehouses)
- Details on how the blood product is processed and stored (including: collection, pooling,
- filtration, heat treatments, purification processes, packaging, storage and transport)
- An explanation of the controls in place to demon strate a low risk of cross contamination or adul teration throughout manufacturing and supply chain
- Product details including the product name, and the volume of individually packaged units

This process will allow the department to determine whether risks associated with product integrity and/or cross contamination are managed appropriately. These measures aim to establish product traceability and achieve an appropriate level of biosecurity risk management.

Relevant details regarding the supply chain for these goods will also be included in the import permit conditions. Where required, these details will also need to be certified by the country of export.

IFBA Sample SOPS

IFBA have provide a series of SAMPLE SOP templates for our members use (Available on the ABSANZ website) these include:

- Biosecurity and Pathogen accountability
- Employee Biosafety Orientation Training
- Accident and incident reporting
- Laboratory Inspection
- Institutional Biosafety Manual
- Transport of Infectious materials
- The use of biological safety cabinets

Members are reminded that these documents have been developed as globalized documents and some of the recommendations and standards may not be in accordance with the requirements of the local area. ABSANZ are grateful to IFBA for providing these documents

"Safe, Secure and Responsible Work with Biological Materials"
International Federation of Biosafety Associations

EBSA 2018 Conference

Article prepared by Neil Walls

The European Biosafety Association (-www.ebsaweb.eu) annual conference took place from 19 to 20 April 2018 in Copenhagen, Denmark. The conference was well organised, with a similar format to our ABSANZ conferences overall.

This included workshops before the conference, a welcome reception, two days of conference with a conference dinner after the first day, and some tours/trips of interest. Of particular interest to some being a visit to a brewery at the University with ample time for trying out the manufactured goods.

Some interesting differences:

1. The conference itself was arranged at a lower budget to ours and took place at University campus buildings. The pre-conference workshops took place at the University of Technology, a good 20-30 minutes' drive from the main conference event at the Faculty of Health and Medical Sciences, University of Copenhagen. These organisations sponsored the event.

2. Accommodation was not available at either location. The organisers listed several hotels; these were about 20 minutes' walk from the conference venue. Fortunately, the weather was great, and the daily walks were very pleasant.

3. The sessions themselves were nearly all plenary. The only exception was the second morning session on day 2, which was a break-out arrangement comprising 5 simultaneous presentations. (I would have liked to attend at least two of these; possibly three)

The conference presentations themselves were varied and very interesting. You can view the programme at http://ebsaweb.eu/ebsa21-conference-copenhagen-2018 if you are interested. I do not have space allocated to run through what I attended and what I learned, but I will describe one presentation which really made me think a lot about risk assessment.

Before the risk assessment is born???!!!

We all, I think, go along with the risk assessment matrix to establish how to characterise hazards, and then decide what we should do about them. We start off with identification of the hazard, we assess the likelihood or probability of its occurrence, we assess the consequence or harm severity of the undesirable event occurring, and we then insert this information into a risk matrix to ascertain what action is required. Once we have applied some risk mitigation strategy (ies), we re-apply the matrix until the residual risk has been reduced to an operationally acceptable level.

For example, the consequence or harm severity could be:

- Catastrophic – multiple deaths
- Critical – one death or multiple severe injuries
- Marginal – one severe injury or multiple minor injuries
- Negligible – one minor injury

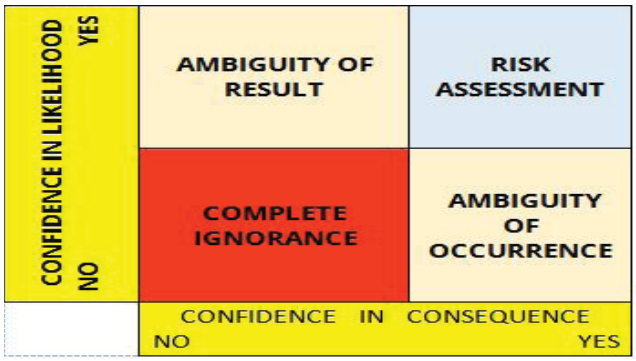
The likelihood or probability of harm occurring might be categorized as 'certain', 'likely', 'possible', 'unlikely' and 'rare'.

	Negligible	Marginal	Critical	Catastrophic
Certain	High	High	Extreme	Extreme
Likely	Moderate	High	High	Extreme
Possible	Low	Moderate	High	Extreme
Unlikely	Low	Low	Moderate	Extreme
Rare	Low	Low	Moderate	High

This approach, though, is reliant upon two critical factors which are sometimes "assumed" but should be stated and understood. These are:

1. That we have successfully identified all the relevant applicable hazards
2. That the persons performing the assessment of likelihood and consequence are suitably knowledgeable, qualified, experienced and trained to do so

Herein lies the importance of ensuring these processes are carried out by a suitable combination of persons who will assess the hazards on their merits alone, and without the encumbrances of public opinion, financial burden, time expediency, etc., influencing the outcome.



The above is a graphical representation of when a risk assessment can be useful and what can go wrong if we have not ensured that we have the knowledge and skills to perform the risk assessment in the first place. For those of you who are interested, go on line to "The epistemology of risk" and open the "Stanford Encyclopedia of Philosophy" link for some interesting reading. I can assist if you need.

The next EBSA conference is programmed for 02 to 05 April 2019 in Bucharest, Romania.

ED Note: Apologies to Neil – Newsletter committee have been holding onto this article for so long that we will be able to get a 2019 EBSA conference update. Thankyou Neil for your contribution.

Handy Resources for ABSANZ members

IFBA have kindly forwarded on a very useful paper titled "Altering an appreciative system: le sons from incorporating dual-use concerns into the responsible science education of biotec nologists"

If this is of interest please download before the end of May 2019 as after this time it will be a article that needs to be purchased: https://authors.elsevier.com/a/1YsZA_NmkljF2

Bio-Risks in Airport Arrivals

Stephen Coulter

Original Article Lucy Knight – Weekly Times 20/2/2019

Official government records revealed that 346,000 biosecurity risks items were intercepted at Australian airports and seaports during 2017/2018. Until December 2018 authorities simply destroyed all articles. In the wake of an African Swing fever outbreak Federal government as ordered testing of samples at CSRIO AAHL facility. Since the detection regime started in December 2018 several confiscated articles have tested positive for foot and mouth disease as well as African swine flu.

This is why border security and the ability to safely and reliably detect these organisms is so important to our national economy and ecosystem. That's why a small amount of pain at the Australian and New Zealand airports is worth it.

MEET THE BOARD

In 2018/2019 we welcomed to the board Carl Ramage, Michelle McConnell, Sean Lansley, Richard Sale, Bernadette Bradley.

Richard Sale

I have built a career over many years as an architect focusing on laboratories, containment facilities and hospitals. Through no persuasion of my own I am delighted to say that all three of my children are now studying or practicing architecture – we are considering starting our own practice "the Four Sales." My other two interests apart from labs, is collecting paint stripper (which I try to imagine is really wine) and collecting paper - refer my desk for evidence!

Carl Ramage

I have been actively involved across Asia Pacific assisting Economies identify and action opportunities for regulatory cooperation and efficiency as well as building capability and capacity in biosafety more broadly. My core objectives for ABSANZ are to support and deliver value to members, provide effective advocacy and ensuring regulation and compliance requirements are pragmatic, science based and commensurate to risk.

My main hobby is playing rugby where I am the current Vice President of Victorian Masters Rugby.

Michelle McConnell

As a microbiologist with a keen interest in medical microbiology I have always had an interest in biosafety. This resulted in my becoming the NZ Microbiological Society representative to the CH-026 committee charged with the AS/NZS standard series 2243, a role I continue to hold. I am keen to use the knowledge gained in both my roles to further the goals on ABSANZ.

Fun fact - surviving walking the Inca trail in 2007

Sean Lansley

It is my hope to increase membership numbers in Western Australia and also increase awareness of ABSANZ to include areas and industries that may not have always been deemed as Biosafety oriented.

Fun fact: My interest in Biosafety first started at the tender age of 18 when being tear gassed as part of my ARMY Medics training!

Bernadette Bradley

I was a researcher and I got started into biosafety when there was an opportunity to work with the late great Dr Sylvia Lachberg (founding member of ABSANZ), Biosafety Advisor extraordinaire, at UWA. I thought it would be interesting work and more regular hours than research to fit in with daycare hours. I loved biosafety and now I'm hooked.

Biosafety bugbears: 1) labcoat hooks well. 2) How do we get the air to balance?

ABSANZ welcomes new members at any time during the year - please note that our membership year has recently changed, and will now run 1 July to 30 June annually.

Online Membership

Join now to access all the benefits of membership. Complete the online application now, or you can download an application form complete and submit with your payment to the ABSANZ Office.

Individual membershipis $132 GST Inclusive 2018/19

EDITORIAL COMMITTEE

- Stephen Coulter, Coulter Advisory
- Subramanyam Vemulpad - Macquarie University
- Neil Walls, Neil Walls Consulting
- Barry Wards MPI

Want a bigger role?

The Editorial Committee is a small group of dedicated industry savvy individuals who would really appreciate additional support from the ABSANZ members.

- If you have a desire to contribute articles or have a series of topics that you would like to see us research and publish information on, please let us know - we welcome all input.
- We would also welcome members who would be interested in becoming part of the editorial committee to not only share the duties but to provide a greater diversity in views and opinions on ABSANZ printed material.

CONTACT US

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MEMBERSHIP

Membership benefits

Your membership of ABSANZ provides you with the following benefits:

- Access to "Members Only' content of website, which includes educational materials, discussion papers and useful website links.
- E-Copy of the ABSANZ Newsletter covering significant changes and events affecting biosafety.
- Discounts to ABSANZ webinars
- Discounts on conference, training and workshops run by ABSANZ. Exclusive opportunities to provide conference and workshop materials at ABSANZ events.
- Access to LinkedIn group, providing a secure chat space to access and share expertise, network with other Biosafety professionals and keep abreast of developments in biosafety.
- Receive news of significant changes and events affecting biosafety.

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Personal information collected by ABSANZ is treated as confidential and is protected by the Privacy Act 1988.

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By becoming an ABSANZ Member you agree to the terms and conditions below and any other terms, conditions, disclaimers displayed elsewhere on this website and in the Constitution.
All interested persons worldwide are eligible for membership.

- The ABSANZ subscription fee is for 1 year, commencing 1 July
- The annual subscription fee is non refundable and non transferrable, except in the case of Membership, where each can be transferred once per year.
- The information you have provided is true and correct.
- ABSANZ reserves the right to cancel or refuse to renew any membership at any time at its own discretion.