

UTas IBC Secretary's Report on the 2006 National Institutional Biosafety (IBC) Forum

Background

The Office of the Gene Technology Regulator (OGTR) held the second National Forum at the National Museum of Australia, Canberra on the 15 and 16 November 2006. Due to continuing changes to OGTR documentation, the OGTR website must be the primary reference source for all documentation and a print as required policy is the only procedure at this time.

Review of the Gene Technology Act and the Gene Technology Regulations.

The reviews of the Act and the Regulations are almost completed. The new Regulations will come into effect on 31 March 2007 and will remove some of the scientific inconsistencies from the Genetic Manipulation Advisory Committee (GMAC) guidelines which were in use prior to the Gene Technology Regulations (GTR). The Forum discussed many important issues regarding the classification of GM animals, classification of complementation experiments, the clarification of dealings with viral vectors and the updated host/vector list. There will further information on the proposed changes available soon on the OGTR website. Changes to the Regs will be first as it does not require passage through Parliament. The changes will be risk based with an outcome focus.

Changes to the Act were recommended by the Independent Review Panel but will take longer to come into effect because of the approvals need to be pass through nine Commonwealth, State and Territory Parliaments and they meet at different times. The revised Act will come into effect about June 2007 but State versions may not be enacted until late 2007. Some of the change will include exempt dealings being truly exempt and not require reporting to the OGTR as presently required. NLRDs can be reported to the OGTR as part of the Annual Report submitted by accredited organisations in place of being reported as approved as presently required. The new Act is almost completed with only the passage through Parliament in all States and Territories to be finalised but the "All of Governments Response to the Independent Panel Recommendations" has been signed by all parties. Secondary amendments to the Regulations will be required once the Act changes.

The legal advice to the Forum was that there may be a time where an accredited organisation may be in breach of the Commonwealth or State Act, depending on the enacted of their respective State approvals. Apparently for a University, the State version of the Act takes precedence. There was advice that the situation is "work to the highest standard" and therefore it may be advisable that if the amended Commonwealth Act takes effect, Accredited Organisations (AO) should wait until their respective State Acts are changed before modifying their processes. AO may have to seek their own legal advice before taking action.

Biotechnology Regulations Online

There is a website that has a portal that will identify all the biotechnology regulations associated with particular proposals by answering the prompts. A link has been placed on the UTas IBC information website. Research Office has been advised of the online database. www.bioregs.gov.au

Certification Guidelines

The next group of guidelines to be reviewed will be PC2 guidelines for laboratories, animal houses and plant houses.

DNIR Licence compliance

The Manager, Contained Dealings and the Manager, Investigations advised that the licence obligations included informing all users on the licence of the licence conditions and that a signed record must be kept of that advice being received by all users. The OGTR requires that the licence holder, the accredited organisation that has been issued the licence and not the Principal Investigator has to have documentation signed by each person working on the licence that states that they have been informed, read and understand the licence conditions OGTR advised that they will be conducting spot audits to ensure that the matter has been addressed.

Gene Technology Ethics Committee (GTEC)

The National Framework for Gene Technology Ethics was launched at the Forum. The Chair of GTEC is Professor Don Chalmers from the Law School, University of Tasmania. The document will be soon available on the UTas IBC information website.

Harmonisation/Alignment

The OGTR briefed the Forum on the progress of harmonisation/alignment for compliance with OGTR, AQIS and Australian Standards, especially Aust Stds PC2 requirements. PC2 accounts for 95% of certified facilities. All three organisations are trying to align as opposed to harmonise, their requirements and the process is progressing. The first joint AQIS/OGTR inspections will be trialled soon but it was determined if that is the AQIS inspection or the third party AQIS inspection. The Forum participants informed the regulators on the importance of the work progressing due to the problems of current conflicts and duplications.

Training of PC2 Facility Users.

DNIR and DIR application forms and licenses list the training required for PC3 and PC4. The Forum provided advice on the training required for PC2 users. The recommended training will be added to the existing PC2 induction form provided by the IBC to users located on the UTas IBC information website. They are mainly procedures already addressed under OH&S procedures but they will be listed as the information answers the old question: "Who trains the trainer". The IBC already provides access to a DVD training program and the IBC will continue to pursue additional training aids if they become available.

Updates from IBC Networks.

Representatives from the state and regional IBC networks updated the forum on their activities over the last 18 months. The Victorian and Tasmanian Network (VTIN) is one of the most active networks and represents the largest group of users in the regulatory network (51 of the 145 accredited organisations are based in Victoria and Tasmania and have made the largest number of submissions to Panels of Review, public consultation etc. It was noted that if the private company were removed then 80% of accredited organisation belong to VTIN, this includes Universities, Institutes etc. VTIN has never has a face to face meeting but it is an aim of the VTIN to have

such a meeting in 2007 with possible a sub group based on the type of organisation i.e. university, and not geographical location.

Observations

The impending changes to the regulatory system will have a significant impact on the current efficient system. There will be many changes to be dealt with in 2007 but eventually the system will accurately reflect the risk associated with the commonly used GMOs. This will be the best practice outcome for users.

There was a collegiate attitude amongst the attendees at the forum. Most of the Research office administration staff from the first forum have been replaced by IBC members due to the nature of the forum.

Rodney Teague
IBC Secretary
Ext 7509
Rodney.Teague@utas.edu.au