Risk Group 2 Organisms

All work with micro-organisms requires the use of standard techniques to minimize risk to the laboratory staff and environment. Such techniques also maintain the purity of strains of isolates in the laboratory. Anyone working with micro-organisms should ensure that they have a thorough understanding of Australian Standard 2243.3:2002 Safety in laboratories Part 3: Microbiological aspects and containment facilities which details these techniques.

AS 2243.3 can be viewed on the Standards On-Line web site accessible through CSU Library Services' web page.

Anyone wishing to import organisms in Risk Group 2 or above must apply to the Biosafety Committee for approval.

Human Biological Specimens

Staff and students conducting teaching and research activities that involves human biological specimens should familiarise themselves with CSU's "Policy for the use of human biological specimens in undergraduate and research laboratories". This policy is contained in the Biosafety Manual (see below).

All human biological samples used should be either from screened donors (i.e. showing negative serology/virology for syphilis, Hepatitis B and C, and HIV) or provided by students who will be testing their own body samples themselves. Anyone conducting teaching and research activities using samples that do not meet these criteria must apply to the Biosafety Committee for an exemption to the policy.

Audits and inspections

All Physical Containment Level 2 facilities (PC2) at CSU are inspected by the Biosafety Committee on a regular basis to ensure they comply with the guidelines from the OGTR. Failure to comply with the regulations may lead to the withdrawal of PC status.

The Biosafety Manual

As part of the regulation of biosafety at CSU, the Biosafety Committee has produced the Biosafety Manual which is available from the committee's website. It is intended to provide guidance to staff and students at CSU who handle or are exposed to potentially biohazardous material during their learning, teaching or research. It contains policies, procedures and guidelines that are intended to *minimise the risk* of infection or injury arising from contact with bio-hazardous material. It also provides some useful general information in the Appendices. It is *not intended* to be a comprehensive manual on all aspects of the safe handling of biological material.

Forms and Guidelines

The following information is available from the Biosafety Committee website:
http://www.csu.edu.au/acad_sec/committees/biosafety/

Forms

- Biological Accident / Incident Report
- Clearance for maintenance work within/to a Biological Facility
- Exempt Dealing Evaluation Reports

Policies, guidelines & procedures available in the Biosafety Manual

- Staff vaccination/inoculation policy
- Policy for the use of human biological specimens in undergraduate and research laboratories
- Procedures for PC2 Laboratories
- Guidelines to assist researchers in the completion of the Exempt Dealing form and Notifiable Low Risk Dealing (NLRD) form
- Guidelines to minimise the risk of HIV/AIDS and hepatitis infection
- Guidelines for staff Mantoux screening
- Guidelines for exposure to bats
- Quality assurance procedures
- Clearance procedures for maintenance work to biological facilities and fixtures
- Procedures for purchasing/acquiring (and notification of arrival of) micro-organisms of Risk Group 2 and above
- Standard Operating Procedures for GMO dealings

The Biosafety website is currently being upgraded. More forms will be available via this site in the near future.

If you have any queries relating to Biosafety please email biosafety@csu.edu.au or call the Biosafety Committee Executive Officer on 02 6338 4091.

CHARLES STURT
UNIVERSITY

BIOSAFETY

in Teaching and Research at Charles Sturt University

Introduction

All staff and students who will be conducting research or practical teaching that involves genetically modified organisms (GMOs) or potentially infectious and/or hazardous agents (including human blood and tissues), or who will be importing biological material, may be required to apply to CSU's Biosafety Committee for approval.

Genetic manipulation

All staff and students who will be conducting research or practical teaching that involves genetically modified organisms (GMOs) should ensure that they have a good understanding of the Gene Technology Act and Regulations. The OGTR has produced a handbook as an aid to the interpretation of the legislation (http://www.ogtr.gov.au/pubform/handbook.htm). Much of the following information has been taken directly from the handbook.

It is the responsibility of individuals to ensure that they are compliant with the legislation. Harsh penalties exist for both individuals and organisations found guilty of non-compliance.

The Gene Technology Act

The *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* came into force on 21 June 2001. This legislation was developed in consultation with all Australian jurisdictions over a number of years to establish a nationally consistent regulatory system for gene technology. The Act introduced a national scheme for the regulation of GMOs, in order to protect the health and safety of Australians and the Australian environment by identifying risks posed by, or as a result of, gene technology, and to manage those risks by regulating dealings with GMOs.

What does the legislation regulate?

The legislation regulates all "dealings" with "GMOs". The legislation prohibits all dealings with GMOs, subject to a system of authorisations described in the legislation. A person who deals with a GMO (without an appropriate approval) is guilty of an offence under the legislation.

What is a "GMO"?

"Genetically modified organism" (or GMO) is defined in the Act to mean either:

a) an organism that has been modified by gene technology;
b) an organism that has inherited traits from an organism (the initial organism) being traits that occurred in the initial organism because of gene technology; or
c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the Regulations to be genetically modified organisms;

but does not include:

d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
e) an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organism declared by the Regulations not to be genetically modified organisms.

The Act defines gene technology as the modification of genes or other genetic material by any technique aside from:

a) sexual reproduction; or
b) homologous recombination; or
c) any other technique specified in the regulations.

What is a "dealing" with a GMO?

"Deal with" in relation to a GMO is defined in the Act to mean:

a) conduct experiments with the GMO;
b) make, develop, produce or manufacture the GMO;
c) breed the GMO;
d) propagate the GMO;
e) use the GMO in the course of manufacture of a thing that is not the GMO;
f) grow, raise or culture the GMO; or
g) import the GMO;

and includes the possession, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).

What is not regulated under the legislation?

The Act does not regulate:

- human beings, if the human being is a GMO only because they have undergone somatic cell gene therapy;
- somatic cell nuclear transfer (cloning) if the transfer does not involve genetically modified material; and
- organisms that are prescribed in the Regulations as not being GMOs.

What types of approvals are there?

The legislation prohibits all dealings with GMOs unless the dealings with GMOs are "approved" in one of four ways. Subject to certain conditions and requirements being complied with, a person may deal with a GMO if the dealings are:

- exempt dealings with GMOs – these are dealings that have been assessed over time as posing negligible risks. Such dealings do not require licensing because the dealings are known to pose low risk. As an additional precautionary measure, exempt dealings must be contained within a facility and must not involve the intentional release of the GMO into the environment.
- notifiable low risk dealings – these are dealings that have been assessed over time as posing low risks provided certain risk management conditions are complied with. NLRDs must be: notified to the Regulator; conducted within a facility certified to be at least PC2; undertaken within an Accredited Organisation; and if transported, must be transported in accordance with Guidelines issued by the Regulator for the transport of GMOs. NLRDs with GMOs must not be released into the environment.
- licences – all dealings with GMOs (that are not exempt, NLRDs or on the GMO Register) will need to be licensed by the Regulator. There are two types of licences that may be issued by the Regulator – licences for dealings that do not involve the intentional release of a GMO into the environment and licences for dealings that do involve the intentional release of a GMO into the environment.
- GMO Register – dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time. Dealings will not be entered onto the Register until the Regulator is satisfied that the dealings are sufficiently safe that they can be undertaken by anyone, and that safety does not depend on oversight by a licence holder.

Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator (OGTR), (http://www.ogtr.gov.au/) has been established to provide administrative support to the Gene Technology Regulator in the performance of their functions under the Act. The OGTR is resourced to investigate non-compliance with the Act. There are severe penalties for both individuals and organisations who fail to comply with the requirements of the Act.