Types of dealings when working with GMOs

There are a number of different classes of GMO dealings. The type of authorisation required for each class is based on the level of risk that the dealings may pose to people and the environment. These classes of dealings and the respective authorisation processes are described below.

Exempt Dealings

Exempt Dealings are described in Schedule 2 of the Regulations and are a GMO category assessed as posing very low risk. The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. The OGTR does not require annual reporting of Exempt Dealings to the OGTR by the university IBC. Exempt Dealings do not require a specified level of containment. If Exempt Dealings occur in uncertified facilities, those facilities must comply with the AS/NZS 2243.3:2010, Part 3: Microbiological Safety and Containment. The regulator has produced *Guidance Notes for the Containment of Exempt Dealings*, to provide guidance to persons conducting Exempt Dealings. Prior to commencement, approval from the IBC is required. Application forms for Exempt dealings can be found on the Biosafety website and Interact site.

Notifiable Low Risk Dealings (NLRD)

Notifiable Low Risk Dealings (NLRDs) are described in Schedule 3 of the Regulations and are a GMO category assessed as posing low risk to people and the environment provided the risk is properly managed. NLRDs must be approved by the IBC. NLRDs must be conducted by appropriately trained persons and must be transported, stored and disposed of in accordance with OGTR guidelines. NLRDs must be conducted within an OGTR certified facility. CSU has certified PC2 Facilities. Application forms for Notifiable Low Risk Dealings can be found on the Biosafety website and Interact site.

Dealings Not Involving Intentional Release (DNIR)

Dealings Not Involving Intentional Release (DNIR) are described in Schedule 3 of the regulations and must be licensed by the regulator. DNIRs are subject to case by case assessments by the OGTR and a license will only be granted once the OGTR is satisfied that any risks posed by the dealings are able to be managed so as to protect the health and safety of people and the environment. Some examples of DNIR dealings are: clinical trials involving GMOs, genetic modifications that may increase the pathogenicity or toxicity of the GMO, and dealings involving pathogens that require PC3 or PC4 containment. Applications for DNIRs are produced jointly by the chief investigator and the IBC and are approved by the IBC before being passed on to the OGTR. The application documentation should be obtained directly from the OGTR website. Once submitted the OGTR has 90 days to review the application. Then a licence is granted directly by the OGTR. Usually the process requires further information the OGTR may request. DNIRs must be conducted in a PC2 or higher OGTR certified facility.

Dealings Involving Intentional Release (DIR)

Dealings Involving Intentional Release (DIRs) are dealings conducted outside containment facilities, for example GM Crops. DIRs must be licensed by the regulator and applications must include a risk assessment and risk management plan. Applications for DIRs are produced jointly by the chief investigator and the IBC and are approved by the IBC before being passed on to the OGTR. The application documentation should be obtained directly from the OGTR website. The OGTR has default timeframe of 225 working days to decide on a DIR application. If the project is a 'limited and controlled' release the approval timeframe is 150-170 working days.

Synthetically modified organisms (SMO)

Synthetic biology is a multidisciplinary and rapidly evolving field. It can be summarised as the design and construction of new biological parts, devices, systems or whole organisms that do not exist in nature, and the re-design of existing, natural biological systems for research and industrial purposes. The effect of synthetically modified organisms (SMOs) on biological diversity or the environment is not understood.

Currently there is no internationally agreed consensus about a definition or scope of synthetic biology or its potential regulatory and risk assessment challenges. It includes GMOs with modular proteins, bacteria with completely synthesised genomes, gene drives and DNA sequence mutations produced by CRISPR technology that are mutations that could potentially occur in nature but do not. The United Nation's Convention on Biological Diversity (CBD) has formerly urged for regulation and that member countries (which includes Australia) follow a precautionary approach to synthetic biology. The CBDs decision on synthetic biology urges all member countries to:

- Follow a precautionary approach to synthetic biology.
- Set up systems to regulate the environmental release of any synthetic biology organisms or products. These regulations must ensure that activities in one country cannot harm the environment of another.
- Ensure that no synthetic biology organisms are released for field trials without a formal prior risk assessment.
- Submit synthetic biology organisms, components and products to scientific assessments that consider risks to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations.
- Encourage research funds to assess the safety of synthetic biology as well the socio-economic impacts of the technology.

Support developing countries to develop their capacity to assess synthetic biology.