



## **FACT SHEET**

### **Types of GMO Dealings**

Dealings with genetically modified organisms (GMOs) are regulated in Australia under the *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001* (the Regulations), which provide for 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 GMO dealings and the respective authorisation processes are described below.

#### **Dealings Involving Intentional Release (DIR) licences**

A licence from the Gene Technology Regulator (the Regulator) is generally required for any dealing involving intentional release (DIR) of a genetically modified organism (GMO) into the Australian environment. This is the most highly scrutinised category of dealings.

The Act sets out the steps that the Regulator must follow before issuing a DIR licence. Key requirements include:

- a rigorous case by case scientific evaluation process that involves the preparation of a comprehensive risk assessment and risk management plan (RARMP) to identify potential risks to human health and safety and the environment and ways of managing those risks; and
- extensive consultation with a wide range of experts, agencies and authorities, and the public.

The Regulator must not issue a licence unless 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.

The default timeframe for the Regulator to decide on a DIR application is 255 working days. However, if the application meets the criteria outlined in Section 50A of the Act for a 'limited and controlled release' application (including proposing containment measures and that the principle purpose is research), the Regulator must decide on the application within 150 working days, or 170 working days if the Regulator considers that the dealings may pose a significant risk.

DIR licences are subject to conditions which must be complied with. These include both statutory conditions, such as reporting requirements regarding the release, and specific conditions to manage any identified risks. Limited and controlled release licences also include conditions to limit the release to the location, size and duration proposed by the applicant and to restrict the spread and persistence of the GMO in the environment.

## **Dealings Not Involving Intentional Release (DNIR) licences**

A licence from the Regulator is required for some dealings with GMOs which are conducted in contained facilities certified by the Regulator. Contained GMO dealings which do not meet the criteria outlined in the Regulations for Exempt Dealings or Notifiable Low Risk Dealings require a licence, and are referred to as dealings not involving intentional release (DNIRs). DNIRs are subject to case by case assessments by the Regulator.

Some examples of the types of dealings requiring a DNIR licence are: clinical trials involving GMOs, genetic modifications that may increase the pathogenicity or toxicity of the GMO, and other higher risk dealings (such as dealings involving pathogens that require physical containment (PC) level PC3 or PC4).

The Regulator must not issue a licence unless 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. The Regulator must decide on a DNIR licence application within 90 working days.

DNIR licences are subject to conditions which must be complied with. These include statutory conditions, such as reporting requirements, and specific conditions to manage risks, such as specification of work practices and of the facilities and physical containment level in which the work must be conducted (e.g. PC2 or higher).

## **Inadvertent Dealings licence**

The Regulator may issue a licence authorising the safe disposal of a GMO to a person who has come into possession of the GMO inadvertently. Issuing of an inadvertent dealing licence does not require the full assessment process required for other applications.

## **Notifiable Low Risk Dealings**

Notifiable Low Risk Dealings (NLRDs) are a category of dealings that have been assessed as posing minimal risk to the health and safety of people and the environment provided certain management conditions are met. Types of dealings which are NLRDs are described in Schedule 3 of the Regulations. The dealings must not involve the intentional release of GMOs into the environment.

NLRDs do not require case by case approval by the Regulator. However before work involving an NLRD can commence it must be assessed by an Institutional Biosafety Committee (IBC). Organisations must keep a record of all current NLRDs, and must include a copy of the record for all new NLRDs as part of their annual report to the Regulator. NLRDs must be conducted in accordance with relevant regulations and must be conducted in an appropriate containment facility (usually a facility certified by the Regulator to PC2 or PC1).

## **Exempt Dealings**

Exempt dealings are dealings that have been assessed over time as posing negligible risks to the health and safety of people and the environment. They comprise basic molecular biology techniques that are used extensively in laboratories worldwide. The criteria for classification as exempt dealings are specified in Schedule 2 of the Regulations.

Exempt dealings do not require an approval from, or notification to, the Regulator, and they do not require a specified level of containment. However, they must not involve an intentional release of the GMO into the environment. The Regulator has produced *Guidance Notes for the Containment of Exempt Dealings*, to provide guidance to persons conducting exempt dealings.

## **The GMO Register**

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied are sufficiently safe that they can be undertaken by anyone, and that safety does not depend on oversight by a licence holder. Any GMO dealings proposed for the Register must first have been licensed by the Regulator. GMO dealings placed on the GMO Register may still be subject to conditions.

## **Emergency Dealing Determination (EDD)**

The EDD provisions in the Act provide the Minister power to expedite the approval of a dealing with a GMO in an emergency. This recognises that situations may arise in which a rapid assessment of a proposed dealing with a GMO may be required.

Before making an EDD, the Minister must be satisfied that:

- there is an actual or imminent threat to the health and safety of people or to the environment;
- the dealings proposed to be specified in the EDD would, or would be likely to, adequately address the threat; and
- any risks posed by the dealings proposed to be specified in the EDD are able to be managed in such a way as to protect the health and safety of people and to the environment.

The Minister must receive advice from: the Commonwealth Chief Medical Officer, the Commonwealth Chief Veterinary Officer or the Commonwealth Chief Plant Protection Officer in relation to the threat and the ability of the GMO to address the threat; and from the Gene Technology Regulator in relation to management of risks. The Minister must also consult the States and Territories before making an EDD.

An EDD can only be made for a limited period (up to six months) but may be extended by the Minister with the agreement of a majority of jurisdictions.