



CHANGES TO DIR LICENCE APPLICATIONS

Changes to the *Gene Technology Act 2000* (the Act) have been made, commencing on 1 July 2007, to streamline the process for the initial consideration of applications for the intentional release of GMOs to the environment. This will be achieved by separating Dealings involving Intentional Release (DIR) into two categories: 'limited and controlled' releases (such as field trials); and 'other' releases (such as commercial releases). The same (revised) DIR application can be used for both categories and the Regulator will use information supplied by the applicant to determine the appropriate category, on a case-by-case basis.

'Limited and Controlled' releases

This new category recognises that an application for release of a GMO for experimental purposes will usually be limited in terms of time, spatial scale and location. The consultation process for a 'limited & controlled' release is consequently simpler than for a 'general' release application .

In order for an application to fit into the 'limited & controlled' category it must satisfy **all** the requirements of section 50A of the Act, including:

- the principle purpose is to conduct experiments; **and**
- it is limited in scope, size, location and duration; **and**
- it has controls to prevent dissemination or persistence.

The new limited and controlled DIR category will have a:

- statutory 150¹ working day time limit for the decision on an application
- minimum 30-day consultation with the public & prescribed experts, agencies and authorities on the Risk Assessment and Risk Management Plan (RARMP)¹.

'Other' releases

Any DIR application that not does satisfy **all** the requirements of section 50A of the Act will fall into this category. This includes releases that are:

- commercial **or**
- non-experimental such as seed increase; **or**
- unlimited in size, location and/or duration; **or**
- minimally controlled to prevent dissemination or persistence.

This DIR category will have:

- 255 working days for assessment - in alignment with similar regulatory bodies such as FSANZ, TGA and APVMA²
- the same consultation requirements as applied prior to 1 July 2007 *i.e.* two minimum 30-day consultation rounds (i) a consultation with prescribed stakeholders on the application and (ii) a second consultation round with the public, prescribed experts, agencies and authorities on the RARMP³.

More information about the changes can be obtained from the Office of the Gene Technology Regulator website at www.ogtr.gov.au, by email to ogtr@health.gov.au or by telephoning 1800 181 030.

¹ If the Regulator identifies a significant risk involved in the proposed release then the public consultation will be extended to 50 days and the evaluation period increased to 170 working days

² FSANZ – Food Standards Australia New Zealand; TGA – Therapeutic Goods Administration; and APVMA – Agricultural Pesticides & Veterinary Medicines Authority

³ If the Regulator identifies a significant risk involved in the proposed release, the second consultation round will be extended to 50 days (but still within the 255 working day time limit)