



Australian Government

Department of Health

Office of the Gene Technology Regulator

## FACT SHEET

### Changes to the Conduct of Notifiable Low Risk Dealings as a Consequence of the Gene Technology Amendment Regulations 2011

#### *Oversight of Notifiable Low Risk Dealings (NLRDs)*

Requirements in the Regulations with respect to dealings with GMOs classified as NLRDs changed on 1 September 2011, as a result of the amendments to the Commonwealth Regulations. These involved changes to Regulations 12, 13 and 13A as well as the introduction of new regulations 13B and 13C.

The requirements for conducting an NLRD are detailed below.

#### *Legislative background to NLRDs*

Unlike for licensable dealings, dealings with GMOs classified as NLRDs do not require case by case assessment by the Gene Technology Regulator (the Regulator). However, NLRDs do require assessment by an Institutional Biosafety Committee.

Part 3 Division 2 of the Regulations, specifically regulations 12, 13 and 13A, govern the classification and conduct of NLRDs.

Dealings that fall under Parts 1 and 2 of Schedule 3, of the Gene Technology Regulations 2001, do not involve intentional release into the environment, and conducted in accordance with Regulations 13 and 13A are NLRDs.

Under section 37 of the Act, it is an offence if NLRDs are not undertaken in accordance with the Regulations.

#### **What (is an NLRD)?**

Parts 1 and 2 of Schedule 3 of the Regulations list dealings with GMOs that have been classified as NLRDs. Part 3 of Schedule 3 qualifies Parts 1 and 2, and lists dealings with GMOs that are **not** NLRDs and therefore require a licence.

An IBC must have assessed that a dealing specified in a written proposal is an NLRD as per Part 1 and Part 2 of Schedule 3 of the Regulations **and** does not involve a release into the environment.

However, it is important to note that listing of dealings with GMOs in the Regulations as NLRDs does not, of itself, provide or equate to authority to conduct those dealings. The dealing must be conducted in accordance with regulation 13 (1) and 13 (2). The scope of the dealing is constrained to that described in the IBC's record of assessment.

## Who?

A person or an accredited organisation must prepare and submit a written proposal for an IBC to assess the dealing is an NLRD.

Only persons who have been assessed by the IBC as having appropriate training and experience may conduct the dealing. This includes persons involved in all parts of the dealing e.g. researchers, couriers and waste contractors.

The person must keep and be able to give, on request, a copy of the IBC's record of assessment to an inspector.

## Where?

As specified in amended regulation 13(2):

- NLRDs classified under Part 1 of Schedule 3 of the Regulations must be conducted in a facility (or class of facilities) that is certified to at least a PC1 level and that is mentioned in the IBC record of assessment as being appropriate for the dealing;
- NLRDs classified under Part 2.1 of Schedule 3 of the Regulations must be conducted in a facility (or class of facilities) that is certified to at least a PC2 level and that is mentioned in the IBC record of assessment as being appropriate for the dealing;
- Under Part 2.2 of Schedule 3 of the Regulations, NLRDs that involve dealings with risk group 3 GM micro-organisms (AS/NZS 2243.3:2010) must be conducted in a facility (or class of facilities) that is certified to at least a PC3 level and that is mentioned in the IBC record of assessment as being appropriate for the dealing; or
- NLRDs may be undertaken in a facility to which the Regulator has agreed to in writing.

**Transport, storage and disposal (TSD)** of GMOs may be conducted outside a certified facility but must be in accordance with the *Guidelines for the Transport, Storage and Disposal of GMOs* or other TSD requirements to which the Regulator has agreed to in writing.

## When?

The Amendment Regulations introduced a 5 year time limit on the conduct of NLRDs but also provided for a phased review of NLRDs assessed and notified prior to commencement of the five year time limit provisions (regulation 13A). The following time limits applied.

NLRDs must only be conducted from the date of assessment by the IBC until:

- **31 March 2015**, if the IBC assessment was **before 31 March 2008**.
- **31 August 2016**, if the IBC assessment was **between 31 March 2008 and 31 August 2011 inclusive**.
- **5 years after the assessment**, if the IBC assessment was **on or after 1 September 2011**.

**Note:** The 5 year limit also includes transport, storage and disposal of the GMOs.

## How?

Persons conducting NLRDs must undertake them:

- in accordance with the conditions of certification of the facility; and
- in accordance with the requirements of the *Guidelines for the Transport, Storage and Disposal of GMOs*.

Importantly, regulation 13(1)(h) requires that ‘a person does not compromise containment of GMOs’. This requirement goes to the behaviour of individuals undertaking NLRDs and is subject to penalties (section 37 of the Act). Behaviour of individuals is an important aspect of containment. Note the requirement of regulation 13(1)(e) for appropriate training and experience.

## Record Keeping and Reporting

IBCs that have assessed an NLRD must give a copy of the record of assessment to the person or accredited organisation that submitted the proposal.

The IBC record of assessment must be in a form approved by the Regulator (see separate document *Guidance for Making Records of Assessment of NLRDs*). The record of assessment must be kept by the person or organisation for 8 years after the date of assessment by the IBC (regulation 13 C).

The person or accredited organisation must provide the information indicated in the NLRD reporting form for NLRDs assessed in the financial year as part of their annual report\* to the Regulator (the notification required by regulation 13C(1)). This form can be found on the OGTR website under Forms – NLRDs.

\* Annual Reports must be lodged by 30 September for the financial year just ended.

## Transitional Arrangements

The amended Regulations provided for transitional arrangements for NLRDs already being undertaken prior to 1 September 2011 where the dealings require a licence after 1 September 2011 (refer to the transitional arrangement in the Amendment Regulations to check whether these provisions apply). If the dealing was undertaken by the same person then it continued to be a NLRD until either a licence was issued by the Regulator to the person for the dealing or 1 July 2012, whichever was earlier.

Similarly, transitional provisions applied for exempt dealings already being undertaken prior to 1 September 2011 where the dealings are classified as NLRDs after 1 September 2011. If the dealing was undertaken by the same person then it continued to be an exempt dealing until either the day on which the IBC assesses the dealing or 1 July 2012, whichever was earlier.