



Review of the Gene Technology Regulations 2001

Discussion Paper No. 4 (2010)

Oversight and Conduct of Notifiable Low Risk Dealings

Legislative background to Notifiable Low Risk Dealings (NLRDs)

Section 74 of the *Gene Technology Act 2000* (the Act) provides for dealings with genetically modified organisms (GMOs) to be declared Notifiable Low Risk Dealings (NLRDs) through scheduling in the Gene Technology Regulations 2001 (the Regulations). Prior to dealings being declared as NLRDs, the Gene Technology Regulator (the Regulator) must have regard to a number of matters related to the containment of the relevant GMO, the level of risk associated with the relevant dealings and the necessity to impose conditions to manage any identified risk. Effectively, dealings will only be scheduled as NLRDs if, having regard to those matters, they are considered by the Regulator to be minimal risk.

Section 75 of the Act further provides for the Regulations to prescribe requirements for the conduct and containment of NLRDs which may include requirements in relation to notification to the Regulator and oversight of NLRDs by Institutional Biosafety Committees (IBCs).

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

Part 3 Division 2 of the Regulations, specifically regulations 12, 13 and 13A, govern the conduct of NLRDs. Only dealings which do not involve an intentional release of a GMO into the environment can be NLRDs.

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.

Oversight of NLRDs – the current situation

Dealings with GMOs classified as NLRDs do not require a licence and therefore may be undertaken without the case by case assessment by the Regulator required for licensed dealings.

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. Dealings may be conducted as NLRDs if:

- the dealings do not involve the intentional release of the GMO into the environment;
- the dealings are scheduled as NLRDs in the Regulations; and
- there is compliance with all the requirements of the Regulations.

Current regulations 13 and 13A provide the framework for oversight of the conduct of dealings with GMOs classified as NLRDs.

A key aspect of NLRD oversight is the requirement for assessment by a properly constituted IBC **prior** to undertaking GMO dealings classified as NLRDs. Before a person can commence dealings classified under the Regulations as NLRDs the following requirements must be met:

- A person must provide information to an IBC about dealings with a GMO which they propose to undertake and which they believe to be an NLRD
- The IBC must have assessed whether the proposed dealings meet the NLRD classification under the Regulations
- The IBC must have advised the person that the dealings have been assessed to be properly classified as NLRDs and that it considers that personnel have appropriate training or experience to undertake the dealing.

Determining if proposed dealings with GMOs are correctly classified as NLRDs is done by reference to Parts 1, 2 and 3 of Schedule 3, ie are the dealings listed in Schedule 1 or 2?

In addition, other requirements of the Regulations must also be complied with:

- NLRDs must be conducted in the physical containment facilities certified by the Regulator that are appropriate for the dealings
- The person (or accredited organisation) must notify the Regulator of the NLRD in an annual report.

Oversight and responsibility for compliance for NLRDs

Responsibility for complying with the requirements of the gene technology legislation, including for NLRDs, rests with the persons or organisations conducting dealings with GMOs.

IBCs represent an important element of Australia's gene technology regulatory scheme. IBCs are comprised of members with the collective technical and scientific expertise to provide expert advice and quality assurance to regulated organisations and individuals, thereby assisting them to comply with the requirements of the gene technology legislation. It is important to note that IBCs are not responsible for the conduct of the persons or organisations that they assist.

IBCs play a key role in the oversight of NLRDs. The IBC assesses NLRD proposals to confirm that proposed dealings with GMOs are properly classified as NLRDs (ie they are listed in Part 1 or Part 2 of Schedule 3 and therefore do not require licensing by the Regulator) and that personnel have the appropriate training or experience.

It should also be noted that the role of the IBC in respect of NLRDs is not to undertake a risk assessment (as NLRDs are already assessed as minimal risk) or to issue an approval *per se*.

For further details on the roles and responsibilities of IBCs and organisations see 'Explanatory Information on the Guidelines for Accreditation of Organisations, 2009' available from the OGTR website at:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accredguideorg-1>

It may be noted that some regulated organisations, as part of their own internal governance processes, confer an operational role on IBCs to ensure organisational compliance with the gene technology legislation by maintaining oversight of dealings with GMOs and certified physical containment facilities. However this is distinct from the roles and responsibilities of an IBC as set out in the Regulations.

Previous reviews of NLRD requirements

The Regulations commenced in June 2001. Historically, the Regulations included detailed information requirements for the preparation and assessment of NLRD proposals and a requirement for prior notification of the Regulator before dealings could commence.

The Gene Technology Amendment Regulations 2006 commenced on 31 March 2007 and removed the detailed information requirements for IBC assessment of NLRDs. This change was the result of a previous review of the Regulations by the Regulator.

The Gene Technology Amendment Regulations 2007 commenced on 1 July 2007 and removed the requirement for the IBC to notify the Regulator before work could commence on an NLRD replacing it with a requirement for the person or accredited organisation to notify the NLRD to the Regulator in an annual report. This change implemented a recommendation of the 2005/6 *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement* (the Statutory Review).

The Statutory Review recommended that the emphasis of GMO regulation be on areas of highest risk, noting that NLRDs are dealings already assessed as low risk.

Current review of regulation 13

Feedback from IBCs and accredited organisations, as well as operational experience of monitoring and compliance activities of the Office of the Gene Technology Regulator (OGTR), has indicated a need to revisit the requirements for undertaking NLRDs.

A number of amendments are proposed to regulations 13 and 13A to clarify the respective responsibilities of persons, organisations, and IBCs in the conduct of NLRDs. The amendments are in four key areas:

- Requirements for assessment and conduct of NLRDs
- Introducing a five year time limit on the authority to undertake NLRDs pursuant to an IBC assessment and notification to the Regulator
- Clarifying the requirements for NLRD proposals and the connection between the proposal assessed by an IBC and the dealings actually undertaken
- Introducing an explicit requirement that persons undertaking NLRDs do not compromise containment of the GMOs.

Proposed changes

Proposal 1 Requirements for assessing and undertaking NLRDs

To clarify the roles and responsibilities of IBCs (regulation 13B) and regulated persons and organisations (regulation 13(1) regarding assessment and conduct of NLRDs, notification of NLRDs to the Regulator (13C, 39(1)(d)) and keeping of records (regulation 13(1)(f), 13B(a) & (b), 13C).

In order to more clearly delineate the requirements and responsibilities for persons or accredited organisations and IBCs in the preparation and assessment of NLRD proposals, and the conduct and notification of NLRDs the following amendments are proposed:

- **13(1)** will include requirements that:
 - NLRD proposals be in writing;
 - an IBC assess the proposal as being an NLRD before dealings commence;
 - dealings undertaken must be those in the IBC record of assessment;
 - dealings must be undertaken in accordance with the five year limit;
 - persons undertaking the dealings must be appropriately trained;
 - an IBC record of assessment be retained;
 - containment not be compromised;
 - NLRDs be undertaken in prescribed physical containment facilities.
- **13(2)** will specify the physical containment (PC) levels of facilities required for the conduct of NLRDs:
 - PC1 for dealings listed in Schedule 3 Part 1
 - PC2 for dealings listed in Schedule 3 Part 2

13(2) will also specify that the facility must be appropriate for the dealing.
- **13(3)** will specify requirements for transport, storage and disposal and qualifies 13(2)
- **13(4)** will specify what the Regulator must consider if approving alternative facilities for the conduct of NLRDs
- **13A** will describe the time limits for NLRDs
- **13B** will detail the responsibilities of IBCs in assessing proposals for NLRDs
- **13C** will detail the requirements for persons and organisations in relation to notification of NLRDs to the Regulator and the keeping of records. The proposed 13C introduces a requirement that persons or organisation must give the Regulator requested information regarding the conduct of an NLRD. It also stipulates that records must be kept by the person or organisation for three years after dealings cease (ie up to five plus three years).

- **39(1)(d)** will also be amended to require notification to the Regulator of the date of assessment of a dealing as an NLRD.
- **Schedule 3 Part 1, 1.1, and Schedule 3 Part 2, 2.1** The introductory paragraphs will be amended to mirror regulation 13(2) by adding “[... facilities] that are appropriate for the dealings”.

In addition, the proposed amendments will clarify that notification to the Regulator is only required for dealings that an IBC has assessed to be appropriately classified as NLRD. Currently there are instances where persons or organisations notify the Regulator regarding NLRD proposals where the IBC has assessed that the dealings are not correctly classified as NLRDs. This is not required.

There has also been some confusion in some organisations in the regulated community about who is responsible for retaining records and reporting about NLRDs. Currently, while 13A(2)(b) indicates that the accredited organisation is responsible for retaining a copy of the IBC’s record of assessment, under 13A(1)(b) an IBC may be required to provide a copy of the same record to the Regulator. It is proposed to remove references to the IBC in relation to keeping and providing records to the Regulator – the Regulator will make requests through the organisation not the IBC. In some instances the IBC is not part of the accredited organisation but is ‘sourced’ from another organisation.

Proposal 2

Introduce a five year limit on NLRDs

Introduce a time limit of five years on the authority to conduct NLRD dealings pursuant to a notification to the Regulator - **proposed regulations 13(1)(d) and 13A**

Provide for a phased introduction of this requirement for NLRDs previously notified to the Regulator.

Introduction of a time limit for conduct of NLRDs through the proposed regulations 13(1)(d) and 13A would address a number of issues related to their effective oversight. This type of amendment has been requested by some IBCs.

Currently, once an IBC has assessed a proposed dealing to be an NLRD, and the organisation undertaking the dealing has notified the Regulator about the particular NLRD in its annual report, there is no further requirement to review or report on the dealing (unless the Regulator requests further information). That is, there is no time limit associated with the authority to conduct a dealing arising from an IBC’s assessment and the organisation’s notification of a proposed NLRD.

Submissions from stakeholders and operational experience of the OGTR indicate that a number of issues related to the oversight of NLRDs potentially arise as a result of this situation.

The potential exists for dealings being undertaken pursuant to a NLRD notification to no longer meet the requirements for classification as a NLRD, because:

- amendments to the Schedules to Regulations (through processes such as this review) change the classification of dealings; or
- the dealings being undertaken inadvertently go beyond those originally proposed to, and assessed by, an IBC (eg dealings change as a research project develops).

In addition, once a NLRD is notified there is no requirement under the Regulations to keep records of whether the dealings are still being undertaken or have ceased. While the GMO Record includes information on all notified NLRDs there is no information on which NLRDs are ongoing at any particular time – such information would increase the transparency of the regulatory system. Many research projects run on a three or five year funding cycle and many NLRDs would be expected to be reviewed or terminated within the proposed five year timeframe.

The dealings with GMOs scheduled as NLRDs have changed with successive amendments to the Regulations. There is currently no provision in the legislation, other than penalties for unlicensed dealings, to require that existing/ongoing dealings previously assessed as NLRDs under a superseded classification be reassessed to ensure they meet the current NLRD classification criteria (noting that specific transitional provisions were included in the Gene Technology Amendment Regulations 2006 in relation to dealings previously scheduled as NLRDs that were reclassified as DNIRs). There might, for example, be dealings currently being conducted pursuant to a notification of, and requirements for, a NLRD but which are now actually classified as exempt dealings.

The proposed amendments provide for a phased review of NLRDs assessed and notified prior to commencement of the five year time limit provisions. These transitional provisions presume an indicative start date of 1 March 2011. If an NLRD was assessed and notified before 1 March 2006 those dealings would not be authorised after 28 February 2013. If an NLRD was assessed and notified between 1 March 2006 and 28 February 2011 those dealings would not be authorised after 29 February 2016. In both cases, persons or organisations would need to submit a new NLRD proposal to an IBC for assessment before they could continue GMO dealings that were previously authorised pursuant to NLRDs previously notified to the Regulator.

However proposed regulation 13(3)(a) provides that transport, storage and disposal of GMOs can occur beyond the five year limit.

Proposal 3

Requirements for NLRD proposals

Clarify that a NLRD proposal to be assessed by an IBC must be in writing (**proposed regulation 13(1)(a)**), and that dealings which may be undertaken pursuant to notification of NLRDs are those dealings specified in the IBC record of assessment (**regulation 13(1)(c) and 13B(a)**)

Since the Gene Technology Amendment Regulations 2006 removed detailed information requirements for NLRDs from regulation 13 the Regulator has received a number of queries from IBCs and accredited organisations regarding the scope of authority provided for NLRDs assessed by an IBC. Experience from OGTR monitoring and compliance activities has also

indicated that the content of ‘proposed dealing’ in regulation 13 is a source of potential confusion for researchers and IBCs. This has ramifications for understanding and complying with the requirements of the legislation in respect of NLRDs. Amendments are therefore proposed which will clarify the scope of NLRD proposals for IBCs and persons or organisations proposing to conduct NLRDs.

The proposed amendments will make it an explicit requirement that a NLRD proposal submitted to an IBC must be in writing (13(1)(a)) and that the authority to conduct dealings is confined to the dealings described in the IBC’s record of assessment (13(1)(c)). This is designed to allow an IBC to describe which particular dealings it has assessed within a broad NLRD category. Only those particular dealings are then allowed to be conducted. As noted above, it is the nature of research projects to develop over time. It is not intended that the operation of this provision unnecessarily limit dealings that may be proposed or undertaken as NLRDs. However persons or organisations will have to give attention to preparing NLRD proposals so that the GMO dealings anticipated for the project are adequately covered.

The responsibilities of IBCs are also clarified by amendments in regulation 13B requiring the IBC to make a record of its assessment.

Proposed amendments will also require that persons or class of persons who will undertake NLRDs are appropriately trained (13(1)(e)) and that the assessing IBC indicates the persons or class of persons who it considers are appropriately trained (13B(iv)).

An IBC assessing a proposal must make a record of assessment in a form approved by the Regulator and give a copy of this record to the person who submitted a proposal (13B(b)), and a person conducting NLRDs must be able to provide an inspector with a copy of the IBC assessment (13(1)(f)). OGTR will develop guidance for researchers and IBCs on what information should be included in an NLRD proposal and an IBC assessment.

Proposal 4 Requirement to not compromise containment

Introduce an explicit requirement that persons undertaking NLRDs do not compromise containment of GMOs (**proposed regulation 13(1)(g)**), and clarify requirements for containment (**proposed regulations 13(2) and (4)**), including for transport, storage and disposal (**proposed regulation 13(3)**) and appropriate training (**proposed regulations 13(1)(e) and 13B(a)(iv)**)

The proposed amendments would clarify the responsibilities of persons and organisations undertaking NLRDs and also clarify enforcement activities for the Regulator and the regulated community.

Regulation 12 stipulates that NLRDs do not involve an intentional release of a GMO into the environment. Regulation 13 details the requirements for undertaking NLRDs and it is an offence under s37(1)(c) of the Act if NLRDs are not undertaken in accordance with the regulations. Section 75(2) of the Act indicates that the Regulations may prescribe requirements to be complied with for NLRDs.

Regulation 13(2) currently indicates the level of physical containment required for NLRDs. Regulation 13(1) details the requirements for undertaking NLRDs, however it does not prescribe any requirements in relation to maintaining containment of GMOs in the conduct of NLRDs. Nonetheless, conditions of Certification for physical containment facilities require certification holders to train personnel in behavioural requirements important for containment of GMOs and require any unintentional releases of GMOs to be reported to the Regulator as soon as possible.

Proposed regulation 13(1)(g) would make explicit a high-level requirement that a person does not compromise containment of GMOs and enable direct regulation of the behaviour of individuals undertaking NLRDs.

Proposed regulation 13(1)(h) would also explicitly require NLRDs to be conducted in appropriate facilities certified to physical containment level PC1 (13(2)(a)) or PC2 containment (13(2)(b)) or in another facility agreed in writing by the Regulator (13(2)(c)).

The proposed 13(2)(c) will replace and simplify the current 13(2)(a)(iii) which enables NLRDs to be conducted in facilities agreed by the Regulator but only pursuant to specific guidelines issued by the Regulator under s27(d) of the Act. Operational experience of the OGTR indicates that unexpected situations can occur which are not covered by the existing guidelines but for which the Regulator can be satisfied that risks to human health and the environment can be adequately managed. The proposed 13(2)(c) will provide the Regulator with flexibility to respond to situations not anticipated by the guidelines, while the proposed 13(4) will still require that the facility be appropriate to the circumstance.

Transport, storage and disposal of NLRDs will be covered by the proposed 13(3) which will require persons to have regard to guidelines issued by the Regulator under s27(d) of the Act.