



Australian Government

Department of Health and Ageing Office of the Gene Technology Regulator

Guidance for making Records of Assessment of NLRDs

As of 1 September 2011, the Gene Technology Amendment Regulations 2011 (Commonwealth) amend the Gene Technology Regulations 2001 (the Regulations). Amendments to regulations 13 and 13A (and the new regulations 13B and 13C) clarify the respective responsibilities of persons, organisations, and Institutional Biosafety Committees (IBCs) in the conduct of Notifiable Low Risk Dealings (NLRDs). These changes will affect the way IBCs record their assessments of NLRDs. The new regulation 13B(a) requires an IBC that has assessed a proposal as being a NLRD to make a record of its assessment, in a form approved by the Gene Technology Regulator (the Regulator), and specifies the information that this record must contain. If the record of assessment (RoA) contains all the information specified in regulation 13B(a)(i)-(x), then this record will be considered to be in a form approved by the Regulator.

Who is this guidance for?

- IBCs - to assist with preparing RoAs of NLRDs (regulation 13B).
- Persons/organisations preparing NLRD proposals (regulation 13A) – to assist with preparing NLRDs proposals as the information provided in a proposal will be used by IBCs when making their RoA. The person/organisation is required to provide a subset of the RoA to the Regulator (regulation 13C).

IBCs and proponents are encouraged to have an interactive proposal dialogue to ensure compliance with the requirements for NLRDs, including making records and reporting.

NLRDs are scheduled in the Regulations, and are dealings with genetically modified organisms (GMOs) that have been assessed as posing minimal risk to the health and safety of people and the environment provided certain risk management conditions are met. In order for a NLRD to commence, the proposed dealing must be assessed and confirmed to be a NLRD by the relevant IBC, and the RoA must be kept by the person/organisation that submitted the proposal.

Figure 1 provides a schematic overview of the roles and responsibilities of the relevant entities for NLRDs. 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>

Note: Regulation 13B (IBC RoA) is intended to sensibly define the scope of a particular NLRD. It clarifies for researchers, organisations, IBCs, and for OGTR compliance activities, what specifically is authorised under a given NLRD. Additional dealings not described in an

original IBC RoA would require a new NLRD proposal by a person/organisation (regulation 13A), assessment by the IBC (regulation 13B) and notification to the Regulator (regulation 13C).

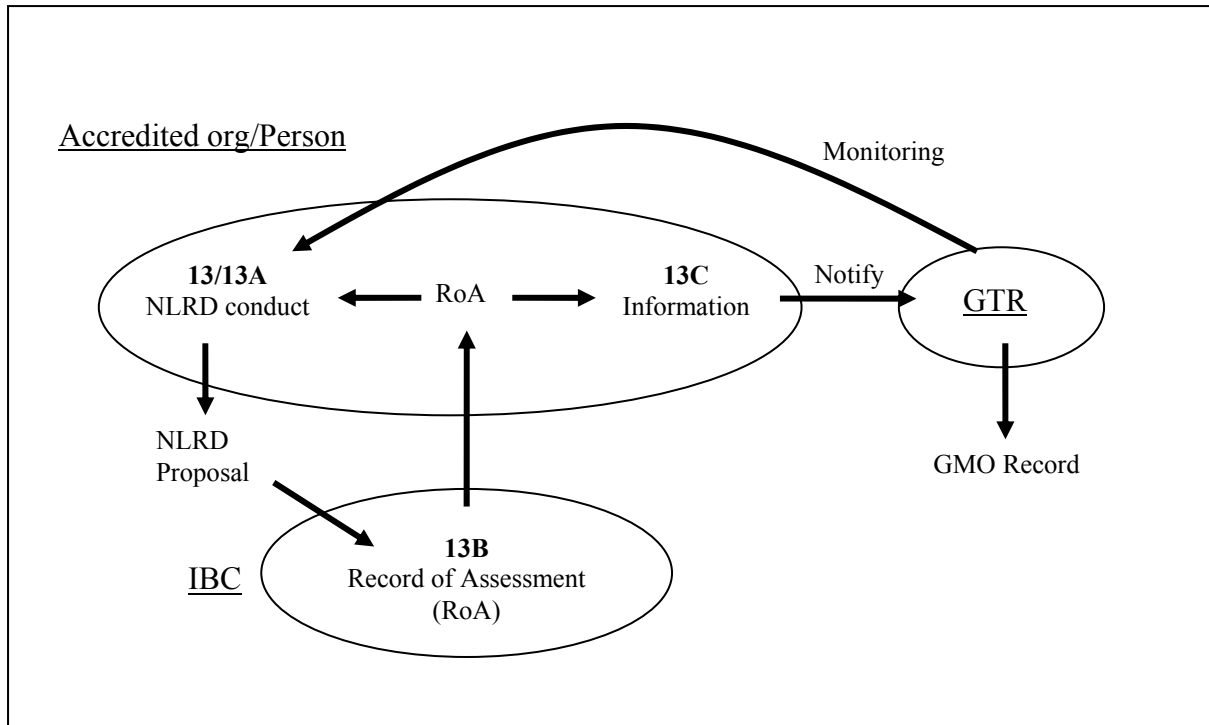


Figure 1. Overview of new regulations 13, 13A, 13B and 13C relating to roles and responsibilities of relevant entities for NLRDs.

GTR: Gene Technology Regulator.

Disclaimer

This guidance document has been prepared to assist IBCs with their record keeping for the assessment of proposed NLRDs. Please note that the information in the table below provides **guidance only** to IBCs and does not constitute legal advice. IBCs assessing NLRDs pursuant to the Regulations and/or pursuant to any applicable corresponding law must refer to the relevant legislation, as current at the time of assessing the dealing.

Amended Regulation 13B (a)	Guidance on information required
<p>An Institutional Biosafety Committee that has assessed a proposal as to whether a dealing is a notifiable low risk dealing <i>must</i>:</p> <p>(a) make a record of its assessment, in a form approved by the Regulator, that includes the following:</p>	<p>IBCs must make RoAs of NLRD proposals.</p> <p>IBCs have the option of using an OGTR ‘model’ form (available on the OGTR’s website under <i>Forms</i>) to make the RoA of proposed NLRDs. Alternatively, IBCs can make a RoA using another recording system (noting that some IBCs/organisations have pre-existing electronic database systems for keeping this information). This allows IBCs to determine the format for recording the information required by regulation 13B(a).</p> <p>It is important to note that, at a minimum, all the information specified in regulation 13B(a) must be included in the RoA. IBCs (and organisations) should satisfy themselves that the RoA does address all requirements of regulation 13B. If the RoA contains all the information specified in regulation 13B(a)(i)-(x), then this record will be considered to be in a form approved by the Regulator.</p>
<p>* (i) the identifying name of the dealing to be undertaken that was given to the dealing by the person or accredited organisation proposing to undertake the dealing</p>	<p>Record a general title for the dealing, as supplied by the accredited organisation or person proposing to undertake the dealing.</p> <p>This title should also be used in the notification to the Regulator (supplied by the person/organisation as required by regulation 13C(1)(a) and 39(1)(c)).</p> <p>Once the NLRD is notified to the Regulator under regulation 13C, the OGTR will assign an OGTR identifier (NLRD number).</p>

* Information to be provided to the Regulator by the person or accredited organisation under regulation 13C (includes information for the GMO record under regulation 39(1))

Amended Regulation 13B (a)	Guidance on information required
(ii) a description of the dealing to be undertaken	<p>It is expected that the description of the proposed project would be written using clear language and would include the following details:</p> <ul style="list-style-type: none"> • common and scientific names of the parent organism(s) of GMO(s) • identity and source of donor nucleic acid, including common and scientific names of donor organisms, if relevant • genetic modification(s), (target genes) • method of genetic modification and expected phenotype/trait/outcomes • a list of the dealings proposed and assessed (this may be all dealings listed in the definition of ‘deal with’ in Section 10 of the Act unless there is a specific reason for excluding one or more of these dealings) • intended use/purpose of the GMOs (eg inoculation into a laboratory animal, cultured <i>in vitro</i> etc). <p>This description should provide sufficient detail for researchers, organisations, IBCs and the OGTR to understand what is specifically authorised.</p> <p>In preparing a proposal (proponent) or describing the dealings to be authorised (IBC), careful consideration should be given to ensuring that it will include all the activities intended to be undertaken. It should not be so narrow as to preclude foreseeable and intended work (which would then need a separate NLRD) nor so broad or general as to lead to confusion about what dealings with the GMOs have actually been proposed and assessed (ie what is authorised).</p>
(iii) its assessment whether the dealing is a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3	<p>Information for this particular subsection should be a simple answer of ‘yes’ (ie the dealing is described within Parts 1 and 2 of Schedule 3).</p> <p>If the dealing isn’t described within Parts 1 and 2 of Schedule 3, it is not a NLRD and no RoA is required. However, if it is not a NLRD, then the IBC should inform the person/accredited organisation why not (eg it is exempt (as defined in Schedule 2) or a DNIR (as defined in Schedule 3, Part 3)).</p> <p>Note – the specific type of NLRD and its required Physical Containment (PC) level as defined in Parts 1 and 2 of Schedule 3 will be specified below in part (iv).</p>

Amended Regulation 13B (a)	Guidance on information required
<p>*(iv) if the Committee has assessed the dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3, the kind of notifiable low risk dealing that the dealing is, in terms of those Parts</p>	<p>List the kind(s) of dealing(s) proposed to be undertaken as a NLRD as specified in Parts 1 and 2 of Schedule 3. As the NLRD may involve a number of scheduled dealings, all the kinds should be listed. Examples:</p> <ul style="list-style-type: none"> • Part 2, 2.1 (m)(iv)(B) (if only one kind of dealing is involved) • Part 1, 1.1, (a) (ii), Part 2, 2.1 (a) (if more than one kind of dealing is involved) <p>Information provided for (ii) (description of dealing to be undertaken) should be considered when determining the kind of NLRD.</p> <p>Note – In determining whether particular dealings are NLRDs, IBCs, and those submitting proposals, should have regard to the entirety of the Schedules. In this context, it should be noted that the properties of the GMOs and the specific activities proposed can impact on whether the dealings meet the criteria for an NLRD or whether they may need a licence. As a specific example, Schedule 3, Part 3 lists dealings that are <u>not</u> NLRDs but would require a licence from the Regulator.</p>
<p>*(v) the date of the Committee’s assessment of the dealing</p>	<p>Record the date the IBC assessed the NLRD.</p> <p>Please note that this date of assessment will be the starting date for the prescribed period of 5 years for a NLRD as described in the new regulation 13A(a).</p> <p>As a matter of convenience, IBCs may wish to calculate the end date of the NLRD and communicate this to the persons/organisation undertaking the NLRD.</p>

Amended Regulation 13B (a)	Guidance on information required
<p>(vi) the persons or classes of persons considered by the Committee to have the appropriate training and experience to undertake the dealing</p>	<p>All persons/classes of persons and their appropriate training/experience should be listed here.</p> <p>The IBC in assessing a proposed NLRD should give consideration to:</p> <ul style="list-style-type: none"> • all persons that may be involved with the dealing for the entire duration of a NLRD. This includes persons beyond the person(s) conducting the research such as persons involved with importation, transportation and disposal of the GMO. • training conducted at the institution/organisation, as well as qualifications and previous experience (eg conducting NLRDs). • dealings that involve specific activities that would require specialist training. • the training requirements of the new <i>Guidelines for the Transport, Storage and Disposal of GMOs</i> (which commence on 1 September 2011 and apply to NLRDs (Regulation 13(3)(b)). • other training requirements such as those specified in the guidelines for certification of physical containment facilities. <p>Consideration should also be given to classes of persons when assessing appropriate training and experience.</p> <p>For example</p> <ul style="list-style-type: none"> • if a service provider is involved in the disposal of laboratory waste, the provider's corporate training and procedures may be appropriate. • research staff/students may be required to complete specific training before working in the institute's laboratories. • if working with animals/injecting animals, staff/students have received specific training.

Amended Regulation 13B (a)	Guidance on information required
<p>(vii) the facilities or classes of facilities the Committee considers to be of the appropriate physical containment level and type for the dealing</p>	<p>The facilities or classes of facilities that are considered appropriate for the dealings should be listed here. It is important to consider all certified facilities that could be involved with the dealing for the entire duration of a NLRD. IBCs must consider both the certification level and type of facility.</p> <p>NLRDs must be conducted in a certified facility (unless otherwise authorised in writing by the Regulator). Particular classes of NLRDs must be conducted in a facility of at Physical Containment level 1 (PC1), PC2 or PC3 (see Regulation 13(2)).</p> <p>Requirements for working in each type of certified facility are generally as per the relevant certification guidelines for the type of facility (noting that individual certified facilities are subject to the conditions of the individual certification instrument).</p> <p>The <u>type of facility</u> (or classes of facilities) should be considered for the type of NLRD and the GMOs involved. For example, dealings with GM plants will generally require housing in certified PC2 Plant Facilities, while large-scale dealings will require the use of a certified PC2 Large Scale facility.</p> <p>In some cases, consideration should also be given to the suitability of <u>individual facilities</u> that are intended to be used. For example, a PC2 laboratory that does not contain a biological safety cabinet may not be appropriate for the conduct of some specific dealings of the NLRD depending on the GMO(s) involved.</p>
<p>*(viii) the name of the Committee that assessed the proposal</p>	<p>Record the name and OGTR number (if known) of the IBC.</p>
<p>*(ix) the name of the person or accredited organisation that submitted the proposal</p>	<p>Record the name of the person/accredited organisation that submitted the NLRD proposal.</p> <p>Note – normally this will be an organisation name, see (x) below)</p>

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Amended Regulation 13B (a)	Guidance on information required
<p>*(x) the name of the person or accredited organisation proposing to undertake the dealing</p>	<p>Record the name of the person/accredited organisation proposing to undertake the notified dealing. This name may be the same as recorded for part (ix) above.</p> <p>Note that the name of the organisation is required for the GMO record (see regulation 39(1)(a)) so, at a minimum, this should be recorded.</p> <p>IBCs/proponents may wish to keep a ‘list’ of more specific details (eg project supervisor, other researchers, whether multiple organisations are involved with the dealings) for their own internal use. This ‘list’ may be subject to change but does not affect the RoA of the dealings as a NLRD.</p>

*Information to be provided to the Regulator by the person or accredited organisation under regulation 13C (includes information for the GMO record under regulation 39(1))

As required by regulation 13B(b), a copy of this assessment must be given to the person or accredited organisation that submitted the proposal to the Committee.