Guidance on making a record of Assessment for NLRD and on responsibilities for those undertaking NLRDs

Notifiable Low Risk Dealings (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.

Regulation 13 specifies the circumstances under which a person may undertake an NLRD. This includes that the dealing must have been assessed by an Institutional Biosafety Committee (IBC) to be an NLRD, and must be undertaken in accordance with the IBC's record of assessment (RoA). Certain information about NLRD assessments must also be provided to the Gene Technology Regulator (the Regulator).

Who is this guidance for?

- IBCs – to assist with preparing RoAs of NLRDs (regulation 13B).
- Persons/organisations preparing NLRD proposals and conducting NLRDs – to assist with preparing NLRD proposals, as the information provided in a proposal will be used by IBCs when making their RoA; and to understand their responsibilities with regard to keeping records and providing information to the Regulator about NLRDs (regulations 13, 13A & 13C).

Disclaimer

Please note that the information below provides **guidance only** and does not constitute legal advice. Persons and organisations proposing or conducting NLRDs, as well as 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.

Responsibility of persons, organisations, IBCs

Regulations 13, 13A, 13B and 13C of the Gene Technology Regulations 2001 (the Regulations) set out the responsibilities of persons, organisations and IBCs in recording and conducting NLRDs. These responsibilities are represented the figure below. Aspects related to the RoA are further detailed under *Preparing a Record of Assessment (RoA) for a proposed NLRD*.

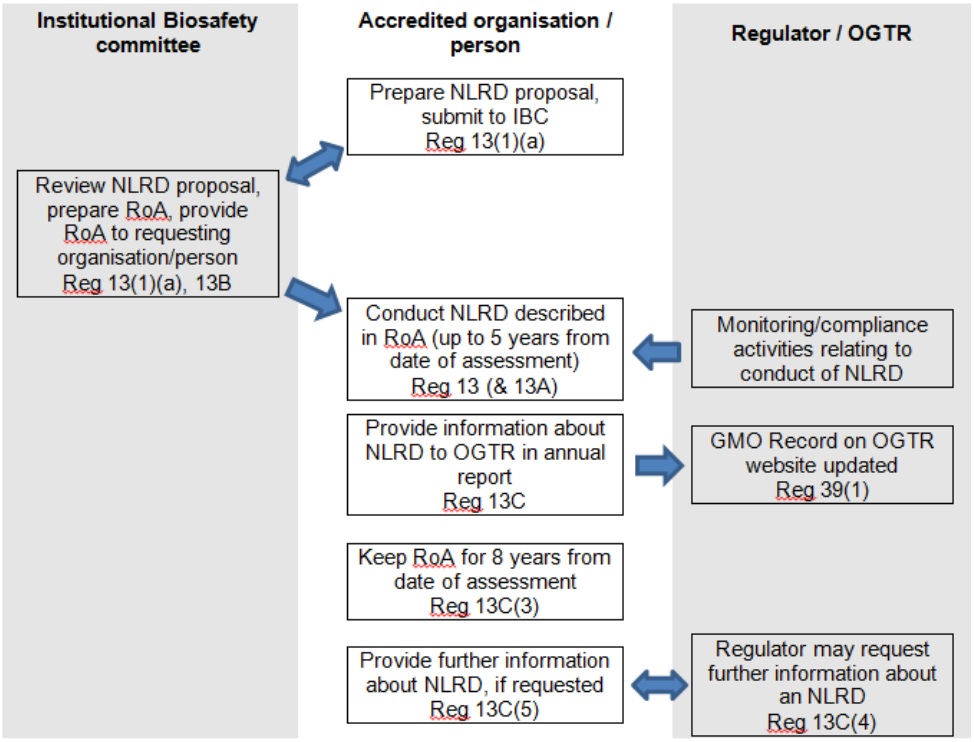

Figure: Overview of roles and responsibilities for NLRDs.

Preparing a Record of Assessment (RoA) for a proposed NLRD

A model NLRD RoA form is available below or from the Forms page, however the Regulations give IBCs the flexibility to develop their own RoA form that covers the information requirements detailed below.

The model form contains a field *IBC Identifier*. This is not a requirement of regulation 13B but is important for both IBCs and the OGTR in keeping track of NLRD proposals and assessment, whether or not the Model form is used. The IBC must assign a unique identifier to each NLRD proposal submitted to it. This can include letters and numerals and other characters, eg. "COL 2016/43". This identifier is also required in the notification of an NLRD provided to the Regulator by the person/organisation in an annual report (regulation 13C(1)). Please do not enter extraneous information in this field such as project title or purpose. Note that once an NLRD is notified to the Regulator under regulation 13C, the OGTR will also assign an NLRD number.

The table below provides guidance on making a RoA that meets the legislative requirements, whether or not the Model form is used.

Regulation 13B requirement	Guidance on information required
An Institutional Biosafety Committee that has assessed a proposal as to whether a dealing is a notifiable low risk dealing ***must***: (a) make a record of its assessment, in a form approved by the Regulator, that includes the following:	An IBC must make a RoA for each NLRD proposal they assess. The RoA must include the information specified in paragraphs (i)-(x). NLRD proponents and IBCs have the option of using an OGTR 'model' form (available on the OGTR's website under *Forms*) to make an NLRD proposal and/or RoA. Alternatively, IBCs can make a RoA using another recording system (noting that some IBCs/organisations have electronic database systems for keeping this information). This allows IBCs to determine the format for recording the information required by regulation 13B(a). If the RoA contains all the information specified in regulation 13B(a)(i)-(x), it is considered to be in a form approved by the Regulator. IBCs (and organisations) should satisfy themselves that the RoA does address all requirements of regulation 13B(a).
*(i) the identifying name of the dealing to be undertaken that was given to the dealing by the person or accredited organisation that submitted the proposal.	This should be a general descriptive title for the dealing, provided by the accredited organisation or person who submitted the proposal.. Note – This title should also be used in the notification provided to the Regulator as required by regulation 13C. Once the NLRD is notified to the Regulator, this title will also be included on the GMO Record (regulation 39(1)). Therefore the title should not include any personal information (e.g. name of project supervisor) or information which may be considered confidential.

(ii) a description of the dealing to be undertaken	Both the GMO(s) and the dealings must be described. The description of the proposed project should be written using clear language and in sufficient detail so that researchers, organisations, the IBC and the OGTR can understand what is authorised (and what is not authorised). The following details should be included: • 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 • method of genetic modification, including any vectors used • details of the genetic modification(s), (e.g. combinations of genetic material introduced, any mutations made in introduced genes, changes to endogenous genes) • expected phenotype/trait/outcomes • a list of the dealings proposed and assessed (in relation to dealings listed in the definition of '*deal with*' in Section 10 of the Act) • intended experiments/activities/use/purpose of the GMOs (e.g. inoculation into a laboratory animal, cultured *in vitro*, isolation of gene products, etc.) 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 (i.e. what is authorised). Any need for import, transport, storage and disposal of GMOs should not be overlooked.
(iii) its assessment whether the dealing is a kind of dealing mentioned in Part 1 or 2 of Schedule 3, and not mentioned in Part 3 of Schedule 3	Should be answered with 'Yes' or 'No' (i.e. the dealing is described within Parts 1 and 2 of Schedule 3, **and** the dealing is **not mentioned** in Part 3 of Schedule 3). Note – In determining whether particular dealings are NLRDs, IBCs and those submitting proposals should have regard to the entirety of Schedule 3. Schedule 3, Part 3 lists dealings that are **not** NLRDs but would require a licence from the Regulator. Therefore, to be an NLRD, the dealing must be of a kind listed in Part 1 or 2 but not listed in Part 3 of Schedule 3. The properties of the GMOs and the specific activities proposed can impact on whether the dealings meet the criteria for an NLRD or need a licence. If the dealing is not described within Parts 1 and 2 of Schedule 3, it cannot be conducted as an NLRD. However, if it is not an NLRD, the IBC should use the RoA to inform the person/accredited organisation of their assessment and reasoning that the proposed dealing is not an NLRD (e.g.

	it is exempt (as defined in Schedule 2) or a DNIR (as defined in Schedule 3, Part 3)).
*(iv) if the Committee has assessed the dealing as being a notifiable low risk dealing mentioned in Part 1 or 2 of Schedule 3 (and not mentioned in Part 3 of Schedule 3)—which kind of dealing in those Parts that the dealing is;	As an NLRD may involve a number of scheduled kinds of dealings, all the relevant kinds that fit the proposed dealings must be listed, as specified in Parts 1 and 2 of Schedule 3. For example: • Part 1, 1.1, (a); Part 2, 2.1 (a); Part 2, 2.1 (m)(i)(ii)(iii)(A) …. Information provided at item (ii) above (description of dealing to be undertaken) should be considered when determining the kind(s) of NLRD. Information about correctly classifying the kinds of NLRDs for reporting online can be found on the Forms page.
*(v) the date of the Committee's assessment of the dealing	Record the date the IBC assessed the NLRD. This date of assessment will be the starting date for the period of 5 years within which the NLRD may be undertaken, as prescribed in regulation 13A(a). As a matter of convenience, IBCs may also wish to calculate and record the end date of the NLRD, being the day 5 years after the date of assessment, and communicate this to the person/organisation that proposed the NLRD.
(vi) the persons or classes of persons considered by the Committee to have the appropriate training and experience to undertake the dealing	The IBC must indicate which persons/classes of persons it is satisfied are appropriately trained &/or experienced to undertaking particular dealings. Note that some persons may have training/experience appropriate for undertaking all dealings described at item (ii) above, while others may be only be appropriate for a specific subset of those proposed dealings. In assessing a proposed NLRD, the IBC should give consideration to: • all persons that may be involved with the dealing for the entire duration of an NLRD. This includes persons beyond those conducting the research, such as persons involved with importation, transportation and decontamination/disposal of the GMO. • training conducted at the institution/organisation, as well as qualifications and previous experience (e.g. conducting NLRDs). • dealings that involve activities that would require specialist training (e.g. animal handling, use of specialised equipment, use of sharps). • the training requirements of the *Guidelines for the Transport, Storage and Disposal of GMOs* (Regulation 13(3)(b). • other training requirements such as those specified in the guidelines for certification of physical containment facilities.

	Consideration should also be given to classes of persons when assessing appropriate training and experience. For example, the IBC may consider the following questions: • If a service provider is involved in the decontamination and disposal of laboratory waste, are the provider's corporate training and procedures appropriate for the dealings of transport and disposal of the GMOs? • If research staff/students are required to complete specific training before working in the institute's laboratories, is a person who has successfully completed this training considered to be appropriately trained for conducting some dealings with the GMOs? • If dealings involve working with animals/injecting animals, do staff/students require additional specific training? If such classes of persons are described, the IBC/proponent may wish to keep a list with more specific details (e.g. project supervisor, individual researchers meeting these criteria) for their own internal use. This list may be subject to change but does not affect the RoA for the NLRD.
(vii) the facilities or classes of facilities the Committee considers to be of the appropriate physical containment level and type for the dealing having regard to the requirements of subregulation 13(2).	The individual 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 an NLRD. IBCs must consider both the certification level and type of facility. Apart from the dealings of storage, transport and disposal, NLRDs must be conducted in a certified facility (or a facility agreed in writing by the Regulator, pursuant to regulation 13(2)(c), which is only intended for exceptional circumstances). Particular classes of NLRDs must be conducted in a facility of at least Physical Containment level 1 (PC1), PC2 or PC3 (see Regulation 13(2)). 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). Dealings with GM plants will generally require housing in certified PC2 Plant Facilities, while large-scale dealings (i.e. dealings involving more than 25 litres of GMO culture in any single vessel) will require the use of a certified PC2 Large Scale facility. However, specific requirements for the particular GMOs/dealings should also be considered in relation to individual facilities or classes of facilities (e.g. specific equipment or procedures). For example, a PC2 laboratory that does not contain a biological safety cabinet may not be appropriate for the conduct of some specific dealings, depending on the GMO(s) involved.

*(viii) the name of the Committee that assessed the proposal	Record the name of the IBC.
(ix) the name of the person or accredited organisation that submitted the proposal	Record the name of the person/accredited organisation that submitted the NLRD proposal. Note – normally this will be an organisation name, see (x) below.
*(x) the name of the person or persons proposing to undertake the dealing	Record the name of the person or persons proposing to undertake the dealing (which may be the same as recorded for part (ix) above). This is required for the GMO record (regulation 39(1)(a)). Note: The name of an individual person is only required here **if** the "person or persons proposing to undertake the dealing" is **actually** an individual who is not associated with an organisation, university, research institute, company etc.
(b) give a copy of the RoA to the person or accredited organisation that submitted the proposal to the Committee.	The IBC must give a copy of the completed RoA to the person or organisation that submitted the proposal, and should have a mechanism to demonstrate that this has been done. The Model Form has a section for recording this action, with signature blocks for the IBC representative and person/organisation that made the proposal. However the IBC may record this action in a different way, such as by saving an email acknowledgement from the person/organisation to whom it has provided the RoA.

***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))**