

Notifiable Low Risk Dealing (NLRD) import template – Explanatory Document

Purpose

This document has been prepared to assist persons or accredited organisations in the completion of the NLRD reporting form to meet their reporting requirements to the Gene Technology Regulator (the Regulator).

Definitions

Record of Assessment (RoA): is required for proposed dealings which have been assessed to be NLRDs by an Institutional Biosafety Committee (IBC).

NLRD reporting form: is the form approved by the Regulator which is to be used to provide a subset of information from the RoA to the Regulator.

Person: refers to individuals or non-accredited organisations undertaking or intending to undertake NLRDs.

Requirements of the NLRD Reporting Process

- a person or accredited organisation must provide the Regulator with a completed NLRD reporting form for dealings assessed to be NLRDs by an IBC. The form must be provided to the Regulator in a report for the financial year (for accredited organisations, this form is part of the annual report).
- a person or accredited organisation that has been given a copy of a RoA by an IBC must keep a copy of the IBC's RoA for 8 years after the date of the assessment.
- a person or accredited organisation cannot vary, transfer or 'renew/extend' a dealing assessed to be an NLRD.
- for an NLRD to be continued past its expiry date, it must be assessed again as a new NLRD (with a new IBC identifier) and notified to the OGTR in the annual report for the reporting period in which the new assessment has been undertaken.
- any intended changes to an NLRD, as detailed in the RoA, may need to be assessed again as a new NLRD (with a new IBC identifier). This is dependent on how the original RoA was written.
- if, as a result of changes, a new NLRD is assessed, it must then be notified to the OGTR in the reporting period in which the assessment has been undertaken.

The NLRD reporting form is available for submission using an online platform which can be accessed from the OGTR website. Details of the required information can be entered into the online form manually or via an importation process. A copy of the NLRD import template is available on the OGTR website.

The content and guidance on completion of the NLRD reporting form is detailed on the following page.

Completing the NLRD reporting form

Note: New field in the NLRD reporting form

An internal review at the OGTR found an increase of collaborative work has led to variation between the organisation submitting the notification of the NLRD and the organisation(s) proposing to undertake the dealing. As a result, the NLRD reporting form for the 2018-2019 reporting period has an additional field that requests organisations to notify the 'Organisation proposing to undertake the dealing'. For many organisations, the 'Organisation proposing to undertake the dealing' will be the same as the organisation that submitted the notification and this information should already be being recorded on all NLRD Records of Assessment, as required by Regulation 13B(a)(x). However, the additional field will allow for multiple organisations to be listed as undertaking the dealing, to address reporting of collaborative research.

Fields in the import template	IBC_Assessed	IBC_NLRD_Identifier	Assessment_Date	IBC_Name	Notifying_Organisation*	Proposing_Organisation	Project_Title*	GMO_Details	Dealing_Type*
Fields in the online reporting form	Has the IBC assessed the proposed dealing to be an NLRD?	IBC NLRD Identifier	Assessment Date	Name of IBC	Name of Organisation Notifying Dealing *	Name of Organisation Proposing to undertake Dealing	Project Title * (please do not include confidential information)	GMO Details	Dealing Type(s)
Guide to completing the fields	<p>Only submit NLRDs to the Gene Technology Regulator that have actually been assessed to be a NLRD.</p> <p>(The answer to this should be "True".)</p>	<p>Enter a unique identifier (this can include letters and numerals and other characters),</p> <p>eg. "COL 2011/43"</p> <p>Please do not enter extraneous information in this field such as project titles/purpose.</p>	<p>This must be a date only (no text) between 21 June 2001 and 30th June of the reporting period (future dates not permitted).</p> <p>Use any date format you wish - the cell will format the date automatically.</p>	<p>This is the IBC used by the organisation. e.g. ABCD Institutional Biosafety Committee.</p>	<p>Name of the organisation that submitted the NLRD proposal to the IBC. This should also be the organisation that notifies the Regulator</p>	<p>Name of the organisation(s) proposing to undertake the NLRD. This can be a number of organisations involved in undertaking the dealing.</p>	<p>Brief project title, for listing on OGTR website (exclude name of the supervisor).</p> <p>DO NOT include any CCI information in the title.</p>	<p>Genus and species (where known) and for viruses, the family. If not known, describe the GMO as best you can. For multiple GMOs, please separate by a comma, or semi colon.</p>	<p>"[1 Sep 2011]" followed by the paragraph number(s) relating to the kinds of dealing relevant for each containment level as detailed in Schedule 3 of the Gene Technology Regulations e.g. [1 Sep 2011] PC1 - (a), PC2 - (a), (m) and (l), PC3</p>

* Fields that will be included in the public list of NLRDs on the OGTR website.