



Australian Government

Department of Health

Office of the Gene Technology Regulator

OGTR Newsletter

Issue 1

Welcome to our first Newsletter

At the OGTR we seek to maintain strong communication with all of our stakeholders. We are trialling this newsletter as part of our communication with Institutional Biosafety Committees (IBCs) and organisations to advise of any updates, changes or news that may affect you and your work with us as well as useful links to assist with processes.

This first issue focuses on Notifiable Low Risks Dealings (NLRDs) as the annual reporting period for NLRDs recently commenced.



Dr Bhula (The Regulator) presenting at the IBC Forum in May 2017

OGTR News & Announcements

- The third review of the National Scheme of the Regulation of Gene Technology by the Legislative and Governance Forum on Gene Technology has commenced. Submissions on the Terms of Reference close on 15 September 2017.
- Accredited organisation annual reports forms for 2016-2017 have been sent to accredited organisations.
- Notification of application DIR 157.
- Documents online concerning Inadvertent Dealings licence for GM petunias.
- The NLRD webpages on the OGTR website will soon be updated with new forms and restructured for easier navigation.
- Thank you to all who presented at and attended the IBC Forum.

15 September 2017

Useful links or special points of interest:

What are Notifiable Low Risk Dealings (NLRDs)?

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/nlrdclass-2>

Information about Institutional Biosafety Committees and their roles and responsibilities with accredited organisations.

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/ibc-1>

Guidance for making Records of Assessment of NLRDs

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/nlrd-record-guide-htm>

Model Form - Record of Assessment Notifiable Low Risk Dealings (NLRDs)

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nlrd-record-htm>

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This issue focuses on common queries regarding the NLRD process. The ‘handy tips’ may assist organisations and IBCs during this reporting period.

NLRDs are dealings with GMOs undertaken in containment that pose low risk to the health and safety of people and the environment provided certain risk management conditions are met.

Organisations conducting NLRDs must have access to an IBC. IBCs assess a proposal for an NLRD and prepare a Record of Assessment (RoA) for each NLRD they assess. Organisations report NLRDs to the OGTR annually.

The list of NLRDs on the OGTR website is updated every year following the annual reporting process.

Handy Tips: RoA

The existing RoA for an NLRD cannot be changed i.e. varied, extended, transferred or amended. A new assessment must be conducted and a RoA prepared to include elements not in the original assessment.

Specific examples of amendments that would constitute a new RoA include:

- Changes to person(s) considered appropriate to undertake the dealings, if not defined by “class”;
- Changes to the class of persons, if defined by class;
- A change to the person(s) or accredited organisation undertaking the dealings;
- Transfer of researcher or person(s) to another organisation;
- Changes to the certified facilities considered appropriate in which to undertake the dealings, if not defined by class ; or
- Changes to class of certified facilities, if defined by class
- Changes to the dealings (e.g. addition of transport and storage if not previously considered)

Next Issue

What to expect and how to prepare for a monitoring and compliance inspection from the OGTR.

*“It is important to never stop questioning”
- Albert Einstein*

Contact

Given that we trialling this newsletter, we’d love to receive your feedback on this issue and suggestions for what you’d like to see in future. We encourage you to email us at ogtr@health.gov.au.

Office of the Gene Technology Regulator (MDP 54)
GPO Box 9848
Canberra ACT 2601

Email: ogtr@health.gov.au
Phone (free-call): 1800 181 030