Australian Government
Department of Health
Office of the Gene Technology Regulator

OGTR Newsletter

Issue #3

OGTR News & Announcements

Date 10 May 2018

- The Office has now relocated to the Woden Town Centre (ACT). This means that our phone numbers have changed, so if you cannot reach an individual please call the OGTR on 1800 181 030.
- Updates on the two ongoing Gene Technology Reviews are as follows:
  - The third review of the National Gene Technology Scheme - Phase 3 consultation on the Preliminary Report has commenced with submissions closing 23 May 2018. The Legislative and Governance Forum on Gene Technology is conducting this review, independent of the Gene Technology Regulator.
  - The Technical Review of the Gene Technology Regulations - the Gene Technology Regulator consulted on proposed amendments to the Regulations from 30 November 2017 to 21 February 2018. The Regulator is now considering the issues raised in submissions and finalising the draft amendments.
- In an effort to make our application process more user-friendly and address a changing technological environment, the OGTR is undertaking a project to explore the use of an online application form system. For the first stage of this project, the Application Entry Point (AEP) section will be trialing two forms;
  - Notification of NLRDs Form – Record of proposed NLRDs; and
  - Application Form for the Certification of a Physical Containment Facility.

  The intention is to have these forms online and ready for use by all applicants by the 30th of June 2018. The office will be seeking assistance from stakeholders to test the newly created forms prior to their release.
- DIR updates:
  - Call for comment on RARMP for commercial release of GM safflower (DIR 158) and clinical trial for respiratory syncytial virus vaccine (DIR 161) and field trial of GM wheat (DIR 162).
  - Notification of application for field trial of GM canola (DIR 163).
  - Notification of a decision to issue a licence for field trial of GM vaccines for farmed crocodiles (DIR 159).
- Significant changes have been made to the information on our website regarding NLRDs. These changes are designed to further clarify the process of NLRD assessment and notification to the Regulator, to make all relevant documents and forms easily accessible, and to be more user friendly and easier to navigate. There is a set of frequently asked questions and answers which we hope that assist stakeholders. Any questions regarding NLRDs, please see the NLRD page via the link below.
- We are soon to commence a review of the effectiveness of the newsletter as a tool to communicate key messages to Institutional Biosafety Committees (IBCs) and applicant organisations. We will be seeking feedback in regards to:
  - the relevance and usefulness of the Newsletter
  - whether the newsletter meets the needs of IBCs and applicant organisations
  - any suggestions for format changes or future topics.

Who evaluates certification applications?
Application Entry Point and Contained Dealings Sections

Useful links or special points of interest:

Online Forms

DIR updates: What's new?

What Are Notifiable Low Risk Dealings (NLRDs)?

The third review of the National Gene Technology Scheme

The Technical Review of the Gene Technology Regulations

Inside this issue:

Feature: Low-level (PC1 & PC2) facility certification processes

The Gene Technology Regulator certifies facilities to specified physical containment (PC) levels and types, for work with genetically modified organisms (GMOs). The majority of applications and certification are for low-level (i.e. PC1 and PC2) facilities. Of the 2063 facilities currently certified, 2014 are low-level certifications. These include laboratories, animal facilities, plant facilities, aquatic facilities, invertebrate facilities and constant temperature rooms. Some application statistics for low-level certifications are presented in the table below, indicating the high volumes.

Application type	Number received in		
	2016	2017	2018 (to date)
New certification	150	138	24
Variation	372	523	205
Suspension	54	75	24
Lift of suspension	35	52	17
Surrender	79	91	51
Transfer	7	2	0

New certification applications have a statutory decision deadline of 90 working days. However if the Regulator needs more information from an applicant, days on which the Regulator is waiting for request information don't count towards this timeframe.

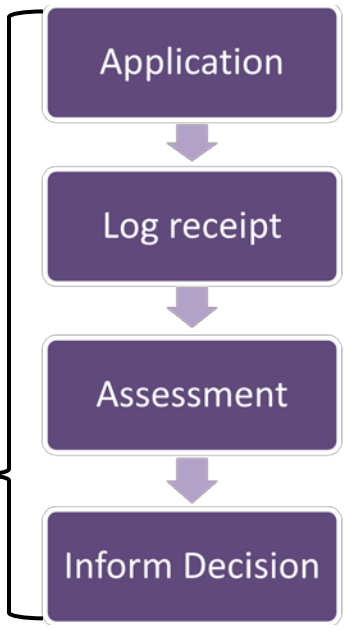
While all certification applications are decided on within this timeframe, simple applications are generally processed much faster than complex ones. Complex applications include those where the floorplan is complex, exemptions from Guideline requirements or conditions are requested (for example, an Animal Facility lacking a dedicated anteroom), or the facility description in the application form doesn't match the floorplan.

No statutory timeframe applies to 'secondary' applications (i.e. requests for variation, suspension, surrender or transfer of a certification). Nevertheless, we generally also process variation applications within 90 working days (and before the expiry date, if relevant) and, as for new applications, simpler ones are finalised more quickly. Surrender and suspension applications are generally processed within 2 weeks.

Recent processing efficiencies

Due to the high volume of low-level certification applications, any small processing efficiencies add up. Process changes implemented in the last year include:

- **Only accepting complete applications**. This applies to new certifications as well as variation requests, including extensions. The application must state that the facility has been inspected and found to comply with the relevant guideline (unless requesting an exemption from a specific requirement, in which case a justification and alternative risk management measures must be provided). For new certifications, all fields of the form must be completed.
- **Assigning a complexity level.** This is helping us to process simple applications (i.e. ones that meet all guideline requirements, have clear floor plans, and aren't missing any information) more quickly.
- **Changes to facility description.** Descriptive text is no longer included in the facility name in the certification instrument, so there will be no need for a variation if you decide to change your facility title (as long as the building name and room numbers don't change).
- **Electronic facility sign.** These are now sent as a pdf which means we can email them as soon as a decision is made.



Tips for applicants:

Following these simple tips can help you meet your regulatory requirements with a minimum of fuss:

Application completeness

- ensure your application is complete and all information is accurate
- cross-check that room numbers, floor level and other details in the application form and floor plan match
- clearly specify the relevant guideline in 'secondary' applications e.g. *Version 3.2 of the Guidelines for Certification of a PC2 Animal Facility*' not '*the relevant guidelines*'
- provide supporting information if requesting an exemption – for example, a justification, risk assessment and proposed risk management strategies to ensure containment of GMOs

Complexity

- where possible, avoid having a single certification encompassing multiple floors, as these are complex to assess and usually require special conditions to manage risks associated with stairs and elevators; and once certified, any issue arising on one floor will impact the whole certification
- variations to extend the period of certification are generally processed according to expiry dates, so as long as you have received an acknowledgement of your application with a variation number, you don't need to follow up weeks ahead of expiry (but please do lodge your extension application in a timely manner – ideally 3-4 months ahead of expiry so we can plan ahead)

Renovation & suspension or variation

- if a proposed renovation will breach the facility boundary, before starting renovations you must apply for, and wait for a decision from the OGTR on, either:
  - suspension of the certification, or
  - variation to remove part of the area from the certification, if the breach can be isolated from the remainder of the facility
- if a proposed renovation will not breach the facility boundary, you will not need to suspend the certification, just ensure the facility (or the affected area of the facility) is decontaminated and all GMOs are appropriately stored before renovation work commences

Communicate with us

- contact us in advance regarding large projects (e.g. new building with multiple certifications, or major refurbishment project) at OGTR.CDES@health.gov.au
- discuss time constraints with us in advance
- lodge all applications at ogtr.applications@health.gov.au.

Next Issue

Tips and Tricks – Confidential Commercial Information

Contact

If you have any suggestions on what you'd like to see in this newsletter, please email us at ogtr@health.gov.au.

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