Australian Government
Department of Health
Office of the Gene Technology Regulator

OGTR Newsletter

Issue 2

OGTR News & Announcements

28 November 2017

- The Office is scheduled to relocate to the Woden Town Centre (ACT) on 15 December. We will inform you of changes to contact details, if you need to contact the OGTR, please call 1800 181 030 or email ogtr@health.gov.au. Please be aware that there may be some delays in responses to queries around this time.
- Updates on the two ongoing Gene Technology Reviews are as follows:
  - The third review of the National Gene Technology Scheme - Phase 2 consultation has commenced with submissions closing 15 December 2017. 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 2001 – is being conducted by the Gene Technology Regulator. The Regulator has published information on the direction of the Technical Review, ahead of consulting on draft amendment regulations expected from late November 2017 until the end of January 2018. The publication of the direction allows stakeholders to provide informed input to the Scheme Review and the longer consultation period is intended to provide ample time for stakeholders to focus on the Scheme Review consultation period as needed. To receive direct notification when the Technical Review draft amendment regulations are available, please subscribe to OGTR News.
- DIR updates:
  - Call for comment on RARMPs for commercial release of GM canola (DIR 155) and GM cotton DIR 157
  - Notification of application for a commercial release of GM safflower (DIR 158)
  - Notification of applications for field trials of GM buffalo grass (DIR 156) and perennial ryegrass (DIR 160)
- In early November, OGTR staff attended the Association of Biosafety for Australia and New Zealand (ABSANZ) conference. ABSANZ is a valuable conference for OGTR to attend, giving staff an opportunity to network with regulated

Feature: Preparing for a monitoring inspection

So you've been selected for an inspection – What happens now?

For announced inspections

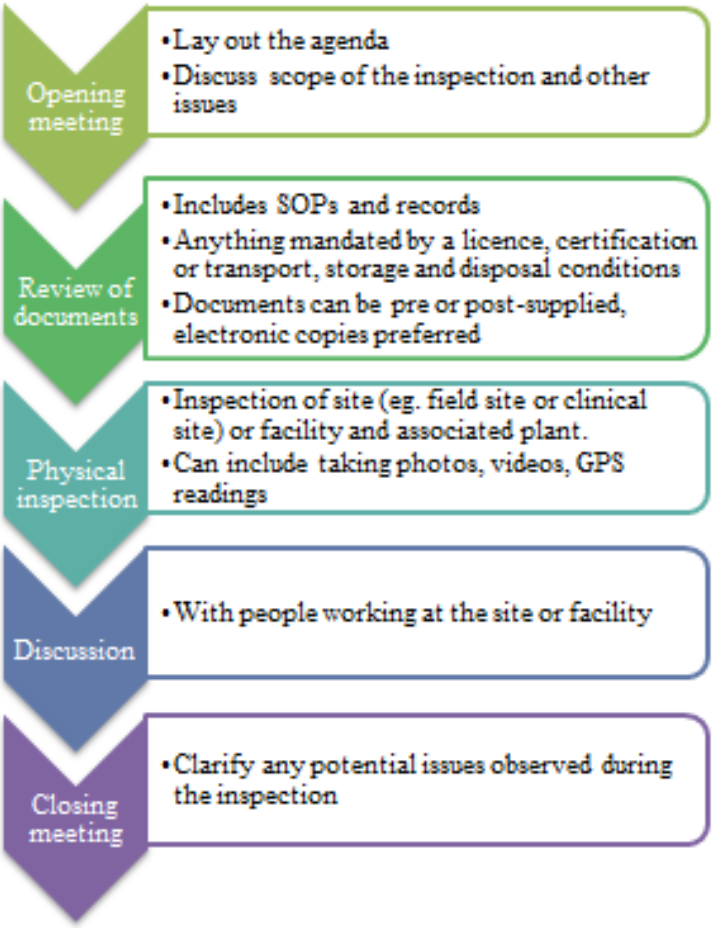
- OGTR will contact you 2 – 4 weeks prior to the inspection date to sort out the logistics and identify any WH&S issues;
- OGTR sets the agenda, but welcomes input from organisations;
- Scheduling conflicts? We can be flexible and may be able to accommodate these needs.

For unannounced inspections you may get up to 90 minutes notice (or you may not)

- We understand that unannounced inspections can occur at inconvenient times – key personnel may not be available, access to facilities limited, etc. We'll do our best to work around any constraints.

Inside this issue:

How might a typical inspection unfold on the day?



Inspection Checklist

Have you...

☐	Provided consent for the inspection? • Someone from your organisation with the authority to do so will need to sign the pre-supplied 'occupiers notice'.
☐	For announced inspections, provided inspectors with contact, location and WHS details? • The email you receive confirming the inspection will usually ask you to supply some information to inspectors in regards to these issues
☐	Provided any requested records? • The types of documents requested will vary depending upon the scope of the inspection
☐	Decided whether you will inform your staff of the inspection? • Advantages of letting them know – you'll probably be able to guarantee their availability • Advantages of surprising them – you'll get a more accurate representation of their level of compliance

What happens after the inspection?

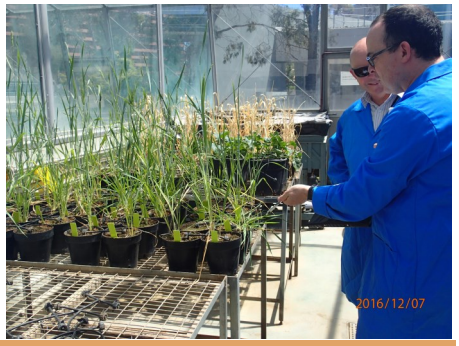
Any potential issues are reviewed in consultation with the relevant evaluation section of OGTR.

- Opportunity to clarify matters with the stakeholder and supply further documentation if required
- Insubstantial issues are ruled out at this point

Substantive issues remaining at this point are then assessed in accordance with Monitoring and Compliance protocols and draft findings are provided to stakeholders.

- Most issues are assessed and resolved via cooperative compliance

All non-compliances are reported in the OGTR Annual Report.



Next Issue

PC 1 and PC2 certification processes: Tips for certification holders and applicants

Contact

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

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