

Quarterly activities report for January – March 2018

The quarterly activities include details of monitoring and compliance activities by the Office of the Gene Technology Regulator (OGTR) during the quarter.

Monitoring of GMO Dealings involving Intentional Release (DIR)

During the quarter the OGTR inspected **eight GM plant field trial sites** (Table 1). The inspections comprised:

- Current field trial sites – Of the **38** sites current in the quarter, **three** were inspected. As these three sites in Deniliquin had never been visited before by OGTR they were selected for routine announced inspections to assess compliance with licence conditions.
- Post-harvest field trial sites – Of the **63** sites subject to post-harvest monitoring in the quarter, **five** were inspected. The sites in Horsham and Ararat were selected for routine announced inspections due to the fact that they had not been previously inspected. The one site in Indigo was selected due to its proximity to sites already selected for inspection and had also not been visited before by the OGTR.

Table 1 – Summary of inspection activities of GM crop field trials for the Jan – Mar 2018 quarter.

| Licence holder | Licence Number | GM Crop | Site location (crop status ¹) |
|--------------------------|----------------|-----------|---|
| Go Resources Pty Ltd | DIR-131 | Safflower | Indigo (1P) Deniliquin (3C) |
| Nuseed Australia Pty Ltd | DIR-123 | Canola | Horsham (2P) Ararat (2P) |

¹C = current site, P = post-harvest site

Monitoring of GMO Dealings Not involving Intentional Release (DNIR), certified facilities and DIR clinical trials

During the quarter OGTR inspected **four** organisations holding certified facilities (Table 2) and **one** undertaking DNIR licences (Table 3).

Table 2 – Summary of organisations and facility types that the OGTR inspected for the Jan – Mar 2018 quarter.

| Organisation | Physical Containment (PC) level | Number of facilities monitored |
|---|---------------------------------|--------------------------------|
| The University of Sydney | PC2 Animal Facility | 2 |
| | PC2 Laboratory | 1 |
| CSIRO Australian Animal Health Laboratory | PC4 Facility | 2 |
| | PC3 Invertebrate | 1 |

| Organisation | Physical Containment (PC) level | Number of facilities monitored |
|----------------------------------|--|---------------------------------------|
| CSL | PC2 Large Scale ² | 2 |
| Baker Heart & Diabetes Institute | PC2 Animal | 1 |
| Total | | 9 |

²Joint inspection with the Contained Dealing Section for re-certification

Table 3 – Summary of inspection activities for DNIR licences and DIR clinical trial licences for the Jan – Mar 2018 quarter.

| Licence holder | Licence number |
|--------------------------|-----------------------|
| The University of Sydney | DNIR-471 DNIR-575 |

Practice Reviews, Audits and Investigations

The Monitoring and Compliance section may initiate Practice Reviews in response to observations made during earlier monitoring activities, or to follow up incident reports. The objective is to determine if licence conditions can be, and are being, effectively implemented.

During the January – March 2018 quarter, two Practice Reviews were conducted to review:

- the suitability of various proposed options for containment of a buffalo grass field trial; this visit complemented assessment of the DIR-156 licence application; and
- the suitability of containment measures and management of contained facilities.

An audit of Macfarlane Burnet Institute for Medical Research and Public Health was also conducted, focussing on facility certification conditions, reporting, and governance arrangements.

Audits of seed breeding companies were conducted in Victoria reviewing their quality assurance processes as part of the OGTR Low Level Presence Strategy. These audits of the industry are ongoing and will be reported in the annual report.

Monitoring and Compliance staff also engaged in continuing professional education and stakeholder engagement activities at the Australasian Environmental Law Enforcement and Regulators network (AELERT) Conference held in the Sydney from 14 to 16 February 2018.

Monitoring and Compliance Findings

Findings from routine monitoring, auditing and investigations, and related enforcement activities, will be provided in the Regulator's Annual Report in accordance with section 136 of the *Gene Technology Act 2000*.