

Quarterly activities report for October – December 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 **14 GM plant field trial sites** (Table 1). The inspections comprised:

- Current field trial sites – Of the **15** sites current in the quarter, **six** were inspected. Sites in the Shires of Merredin, Katanning and Murrumbidgee had never been visited before by OGTR and were selected for routine announced inspections to assess compliance with licence conditions.
- Post-harvest field trial sites – Of the **45** sites subject to post-harvest monitoring in the quarter, **eight** were inspected. A number of sites at Merredin and Katanning were selected for routine announced inspections due to the fact that they were located at new current sites that had not previously been inspected.

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

| Licence holder | Licence Number | GM Crop | Site location (crop status ¹) |
|----------------------------|----------------|----------------|---|
| Monsanto Australia Limited | DIR 147 | Cotton | Murrumbidgee (1C) |
| The University of Adelaide | DIR 128 | Wheat & Barley | Merredin (3C, 5PH) Katanning (2C, 3PH) |

¹ C = current site, PH = post-harvest site.

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

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

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

| Organisation | Physical Containment (PC) level | Number of facilities monitored |
|--|---------------------------------|--------------------------------|
| CSIRO | PC3 Laboratory | 3 |
| | PC3 Animal | 1 |
| Department of Jobs, Precincts and Regions (Victoria) | PC2 Plant | 2 |
| Hospira Adelaide Pty Ltd | PC2 Large Scale | 1 |
| Seqirus Pty Ltd | PC2 Large Scale | 3 |
| South Australian Health and Medical Research Institute | PC2 Laboratory | 2 |
| | PC2 Animal | 1 |
| The University of Queensland | PC2 Laboratory | 2 |
| Western Health | PC2 Laboratory | 1 |
| | PC2 Animal | 1 |
| Total | | 17 |

Table 3 – Summary of inspection activities for DNIR licences for the October – December 2018 quarter.

| Licence holder | Instrument Identifier |
|-----------------|-----------------------|
| CSIRO | DNIR 066 |
| | DNIR 068 |
| | DNIR 387 |
| | DNIR 427 |
| | DNIR 443 |
| | DNIR 496 |
| | DNIR 570 |
| Seqirus Pty Ltd | DNIR 352 |

| Licence holder | Instrument Identifier |
|--|------------------------------|
| The University of Queensland | DNIR 518 |
| Women's and Children's Health Network Incorporated | DNIR 571 |

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 October – December 2018 quarter the OGTR continued its program of Practice Reviews and visited:

- The University of Queensland's proposed trial site for DIR 153 and the Department of Jobs, Precincts and Regions (Victoria) proposed trial site for DIR 160 as part of the Practice Review into *Preparedness of accredited organisations to undertake a limited and controlled release*; and
- Murdoch University, as part of the Practice Review into *Transport, storage and waste disposal*; and
- The University of Western Australia, as part of the Practice Review into *Facility Structure and Maintenance*.

Other activities

Monitoring and Compliance staff also undertook the following additional activities:

- Capacity building activities, to provide guidance and build regulatory understanding, with BioQuisitive Ltd and Alpha Space Pty Ltd

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*.