**Quarterly activities report for April – June 2021**

The quarterly activities include details of monitoring and compliance activities by the Office of the Gene Technology Regulator (OGTR) during the quarter. Due to the COVID-19 pandemic travel restrictions a number of the monitoring and compliance activities for this quarter were conducted in a desktop capacity.

**Monitoring of GMO Dealings involving Intentional Release (DIR)**

During the quarter the OGTR desktop inspected **one GM plant field trial site (Table 1).**

* Current field trial sites- of the **eight** sites current in the quarter, **two** was inspected.
* Post-harvest field trial sites- of the **16** sites subject to post-harvest monitoring in the quarter, **six** were inspected.
* All sites inspected in Queensland, Victoria and New South Wales were selected as routine inspection.

Table 1 – Summary of inspection activities of GM crop field trials for the April – June 2021 quarter.

| **Licence holder** | **Licence Number** | **GM Crop** | **Site location**  **(crop status[[1]](#footnote-1))** |
| --- | --- | --- | --- |
| Monsanto Australia Pty Ltd | DIR 147 | Cotton | NSW (1 PH, 1 C) |
| The University of Melbourne | DIR 165 | Wheat | Vic (2 PH) |
| The University of Queensland | DIR 153 | Sorghum | Qld (3 PH, 1 C) |

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

During the quarter the OGTR inspected **nine** organisations holding certified facilities (**Table 2)** and **five** undertaking a DIR or DNIR licence (**Table 3**).

Table 2 – Summary of organisations and facility types that the OGTR inspected for the April - June 2021 quarter.

| **Organisation** | **Physical Containment (PC) level** | **Number of facilities monitored** |
| --- | --- | --- |
| Austech Medical Laboratories Pty Ltd [[2]](#footnote-2) | PC2 Laboratory | 1 |
| LaTrobe University | PC2 Laboratory | 1 |
| University of Canberra | PC2 Laboratory  PC2 Animal | 4  1 |
| University Wollongong | PC2 Laboratory  PC2 Animal | 5  1 |
| The University of Adelaide | PC2 Laboratory | 7 |
| Western Sydney University | PC2 Laboratory  PC2 Animal  PC2 Plant  PC2 Invertebrate | 2  1  1  1 |
| CSIRO 3 | PC4 Facility | 1 |
| Intervet Australia Pty Ltd 3 | PC2 Large Scale | 1 |
| Monash University [[3]](#footnote-3) | PC3 Invertebrate | 1 |
| **Total** |  | **28** |

Table 3 – Summary of inspection activities for DNIR and DIR licences for the April – June 2021 quarter.

| **Licence holder** |  |  | **Licence number** |
| --- | --- | --- | --- |
| University of Canberra |  |  | DNIR 478 |
| University Wollongong |  |  | DNIR 081 |
| The University of Adelaide |  |  | DNIR 230 |
| TheraVir Pty Ltd |  |  | DNIR 602 |
| Western Sydney University |  |  | DNIR 552 |

**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 or to assess the effectiveness of systems used by licence holders and IBC(s). The objective is to determine if licence conditions can be, and are being, effectively implemented.

During the April – June 2021 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

* Avance Clinical Pty Ltd to undertake licensed dealings not involving intentional release (DNIR-636 – *Clinical trial to determine the safety and efficacy of SC-Ad6-1, an adenovirus based COVID-19 vaccine*) and
* The University of Queensland to undertake licensed dealings not involving intentional release (DNIR-634 - *Dissecting Covid-19 pathogenesis by advanced molecular technologies*).

No audits and no investigations were undertaken during the quarter.

**Monitoring and Compliance Findings**

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

1. PH = post-harvest site; C = current site [↑](#footnote-ref-1)
2. Desktop inspection [↑](#footnote-ref-2)
3. 3 Facilities were subject to joint inspections with the Contained Dealings Evaluation Section for re-certification [↑](#footnote-ref-3)