

## Quarterly activities report for January – March 2022

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 few 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 did not inspect any GM plant field trial sites.

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

During the quarter, the OGTR inspected **two** organisations holding certified facilities (**Table 1**) and **one** DNIR licence (**Table 2**).

Table 1 – Summary of organisations and facility types that the OGTR inspected for the January – March 2022 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Swinburn University of Technology <sup>1</sup>	PC2 Laboratory	2
The University of Queensland	PC2 Plant Facility	5
<b>Total</b>		<b>7</b>

Table 2 – Summary of inspection activities for DNIR licences and DIR clinical trial licences for the January – March 2022 quarter.

Licence holder	Licence number
Pfizer Australia Pty Ltd <sup>1</sup>	DNIR-569

### 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 January – March 2022 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

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<sup>1</sup> Desktop inspection

- Novotech (Australia) Pty Limited (DIR 181) – Clinical trial of a genetically modified Herpes virus for the treatment of cystic fibrosis, as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a limited and controlled release*’

No audits and no investigations were undertaken during the quarter.

### **Other activities**

During the January-March 2022 quarter the Monitoring and Compliance section:

- Attended and presented at the 2022 International Society for Cell & Gene Therapy, Australian & New Zealand – Biotherapeutics Association of Australasia Joint Scientific Meeting which was conducted virtually
- Visited the University of Queensland in response to the flooding at St. Lucia and Gatton campuses

### **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*.