

Quarterly activities report for July – September 2020

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 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 **two GM plant field trial sites (Table 1)**.

- Current field trial sites- of the **five** sites current in the quarter, two were inspected. The sites were in the Northern Territory and were selected for routine desktop inspection.
- Post-harvest field trial sites- of the **33** sites subject to post-harvest monitoring in the quarter, **none** were inspected.

Table 1 – Summary of inspection activities of GM crop field trials for the July – September 2020 quarter.

Licence holder	Licence Number	GM Crop	Site location (crop status ¹)
Queensland University of Technology	DIR 146	Banana	Qld (2C)

¹ C = current 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 **three** undertaking a DIR or DNIR licence (**Table 3**).

Table 2 – Summary of organisations and facility types that the OGTR inspected for the July – September 2020 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Australian Genome Research Facility	PC2 Laboratory	1
	PC2 Plant	1
The University of Queensland	PC3 Animal	2
	PC3 Laboratory	1
Nepean Blue Mountains Local Health District	PC2 Laboratory	1
Curtin University ²	PC3 Laboratory	1
Total		7

Table 3 – Summary of inspection activities for DNIR and DIR licences for the July – September 2020 quarter.

Licence holder	Licence number
Clinical Network Services	DIR 161
The Children’s Hospital at Westmead	DNIR 586
The University of Queensland	DNIR 472

² Facility was subject to a joint inspection with the Contained Dealings Evaluation Section for re-certification

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 July- September 2020 quarter the OGTR continued its program of practice reviews, undertaking virtual meetings with:

- Peter MacCallum Cancer Centre (DNIR-606 – An international phase1/2 study of GRT-C901/GRT-R902, a neoantigen cancer vaccine, in combination with immune checkpoint blockade for patients with advanced solid tumours as part of the practice review into the *Preparedness of accredited organisations to undertake licensed dealings not involving an intentional release*.

No audits and no investigations were undertaken during the quarter.

Other activities

Monitoring and Compliance staff were actively engaged with organisations to provide advice regarding the COVID-19 pandemic.

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*.