

Quarterly activities report for July – September 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 all 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 **three** organisations holding certified facilities (**Table 1**) and **two** undertaking a DIR or DNIR licence (**Table 2**).

Table 1 – Summary of organisations and facility types that the OGTR inspected for the July – September 2021 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Charles Darwin University	PC2 Laboratory	2
CSIRO	PC2 Laboratory	1
	PC2 Plant	1
Telethon Kids Institute	PC2 Laboratory	3
	PC2 Animal	1
Total		8

Table 2 – Summary of inspection activities for DNIR and DIR licences for the July – September 2021 quarter.

Licence holder	Licence number
Ascend Biopharmaceuticals Ltd	DNIR 536
CSIRO	DNIR 618

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 July – September 2021 quarter the OGTR initiated an audit of PGG Wrightson Seeds to review 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.

No practice reviews 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*.