

Quarterly activities report for October – December 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 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 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 **five** organisations holding certified facilities (**Table 1**) and **one** undertaking a DIR or DNIR licence (**Table 2**).

Table 1 – Summary of organisations and facility types that the OGTR inspected for the October – December 2020 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
CSIRO	PC2 Laboratory	2
Therapeutic Goods Administration Laboratories Branch	PC2 Laboratory	4
Teva Pharmaceuticals ¹	PC2 Laboratory	3
Westmead Institute for Medical Research ^{1,2}	PC3 Laboratory	1
Total		10

Table 2 – Summary of inspection activities for DNIR and DIR licences for the October – December 2020 quarter.

Licence holder	Licence number
CSIRO	DNIR 495

¹ Desktop inspection

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 October- December 2020 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

- CSIRO to review preparedness to undertake licensed dealings involving intentional release at the new research station in Boorowa NSW

No audits and no investigations were undertaken during the quarter.

Other activities

During the October-December 2020 quarter the Monitoring and Compliance section were:

- Actively engaged with organisations to provide advice regarding the COVID-19 pandemic;
- Conducted a desktop inspection for a newly certified PC2 Large Scale facility at the University of Technology Sydney with the Contained Dealings Section; and
- Attended the Association of Biosafety for Australia & New Zealand (ABSANZ) Conference Summit 2020 which was conducted virtually.

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*.