

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)
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	PC2 Laboratory	1
LaTrobe University	PC2 Laboratory	1

¹ PH = post-harvest site; C = current site

² Desktop inspection

Organisation	Physical Containment (PC) level	Number of facilities monitored
University of Canberra	PC2 Laboratory	4
	PC2 Animal	1
University Wollongong	PC2 Laboratory	5
	PC2 Animal	1
The University of Adelaide	PC2 Laboratory	7
Western Sydney University	PC2 Laboratory	2
	PC2 Animal	1
	PC2 Plant	1
	PC2 Invertebrate	1
CSIRO ³	PC4 Facility	1
Intervet Australia Pty Ltd ³	PC2 Large Scale	1
Monash University 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:

³ Facilities were subject to joint inspections with the Contained Dealings Evaluation Section for re-certification

- 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*.