

Quarterly activities report for July – September 2023

The quarterly activities include details of monitoring and compliance activities by the Office of the Gene Technology Regulator (OGTR) during the quarter.

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 and veterinary trials

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

Table 1 – Summary of organisations and facility types that the OGTR inspected for the July – September 2023 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Australian Veterinary Serum Laboratories	PC2 Laboratory	1
	PC2 Laboratory	15
CSIRO	PC2 Plant Facility	14
	PC2 Invertebrate Facility	4
	PC2 Animal Facility ¹	4
	PC2 Large Scale Facility	2
QIMR	PC2 Invertebrate Facility	1
	PC3 Laboratory	1
Total		42

¹ = Facilities were subject to a joint inspection with the Contained Dealings Evaluation Section

Table 2 – Summary of inspection activities for DNIR licences, DIR clinical and veterinary trial licences for the July – September 2023 quarter.

Licence holder	Licence number
CSIRO	DNIR 584

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 2023 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

- Australian Veterinary Serum Laboratories (DNIR-662) - Expression of Australian paralysis tick holocyclotoxins in *Pichia pastoris* for development of therapeutics, as part of the practice review into the '*Preparedness of accredited organisations to undertake licenced dealings not involving intentional release*'.
- Janssen-Cilag Pty Ltd (DNIR-669) - Clinical trial of genetically modified adeno-associated virus for treatment of geographic atrophy secondary to age-related macular degeneration, as part of the practice review into the '*Preparedness of accredited organisations to undertake licenced dealings not involving intentional release*'.

During the July – September 2023 quarter the OGTR continued audit activities, during which the OGTR:

- Commenced an audit of QIMR Berghofer Medical Research Institute in Queensland, and;
- Continued an audit of Monash University in Victoria.

Audit findings will be reported in the Regulator's Annual Report once the respective audit has been completed.

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*.