Quarterly activities report for July – September 2022

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 **one** organisation holding certified facilities (**Table 2).**

Table 2 – Summary of organisations and facility types that the OGTR inspected for the July – September 2022 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
CSIRO	PC2 Animal Facility	15
	PC2 Laboratory	1
Total		**16**

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 2022 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

- Westmead Institute for Medical Research Pty Ltd (DIR-183) – Clinical trial with genetically modified *E. coli* to reduce antibiotic resistance, as part of the practice review into the '*Preparedness of accredited organisations to undertake licenced dealings involving intentional release*' and
- Merck Sharp & Dohme (Australia) Pty Ltd (DNIR-650) – Clinical trial of a live attenuated tetravalent Dengue vaccine (V181) in adults, as part of the practice review into the '*Preparedness of accredited organisations to undertake licenced dealings not involving intentional release*'.

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*.