

Quarterly activities report for October – December 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 inspected **four** GM plant field trial sites (**Table 1**).

- Current field trial sites - of the **14** sites current in the quarter, **one** was inspected.
- Post-harvest field trial sites - of the **13** sites subject to post-harvest monitoring in the quarter, **three** were inspected.

Table 1 – Summary of inspection activities of GM crop field trials for the October – December 2023 quarter.

Licence Holder	Licence Number	GM Crop	Site location (crop status ¹)
Monsanto Australia Pty Ltd	DIR 164	Canola	NSW (3 PH)
CSIRO	DIR-162	Wheat	NSW (1 C)
Total			4

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 **four** organisations holding a DNIR licence (**Table 2**).

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

Organisation	Physical Containment (PC) level	Number of facilities monitored
Ozgene ARC Pty Ltd	PC2 Animal Facility	1
Curtin University	PC3 Laboratory	1
	PC2 Laboratory	6
Total		8

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

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

Licence holder	Licence number
Novotech (Australia) Pty Ltd	DIR-140
BioMarin Pharmaceutical Australia Pty Ltd	DNIR-600
Curtin University	DNIR-563
Pfizer Australia Pty Ltd	DNIR-569

Practice Reviews, Audits and Investigations

The Monitoring and Compliance section may initiate practice reviews in response to observations made during monitoring activities, 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 October – December 2023 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

- Novotech (Australia) Pty Ltd (DIR-197) - Clinical trial of genetically modified *Lactobacillus brevis* for treatment of inflammatory bowel disease, as part of the practice review into the '*Preparedness of accredited organisations to undertake licenced dealings involving intentional release*'.

During the October – December 2023 quarter the OGTR did not conduct any audit activities or investigations.

Other activities

Attended:

- 11th Annual ABSANZ Biosafety and Biocontainment Conference
- Australian Regulatory Science Network (RSN) Annual Symposium.

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*.