

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

- Current field trial sites- of the **three** sites current in the quarter, **none** were inspected.
- Post-harvest field trial sites- of the **18** sites subject to post-harvest monitoring in the quarter, **one** was inspected.
- The site inspected in Victoria was selected as routine inspection.

Table 1 – Summary of inspection activities of GM crop field trials for the October – December 2021 quarter.

Licence holder	Licence Number	GM Crop	Site location (crop status ¹)
Department of Jobs, Precincts and Regions	DIR 160	Perennial ryegrass	Vic (1 PH)

Monitoring of GMO Dealings Not involving Intentional Release (DNIR), certified facilities and DIR clinical trials

During the quarter the OGTR inspected **two** organisations holding certified facilities (**Table 2**) and **one** undertaking a DIR or DNIR licence (**Table 3**).

Table 2 – Summary of organisations and facility types that the OGTR inspected for the October – December 2021 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Macquarie University	PC2 Laboratory	6
	PC2 Invertebrate	1
	PC2 Plant	2
Total Livestock Genetics Pty Ltd	PC2 Large Grazing Animal	1
Total		10

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

² Desktop inspection

Table 3 – Summary of inspection activities for DNIR and DIR licences for the October – December 2021 quarter.

Licence holder	Licence number
BioMarin Pharmaceutical Australia Pty Ltd ²	DNIR 600

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 October – December 2021 quarter the OGTR continued its program of practice reviews, undertaking meetings with:

- PTM Solutions Australia Pty Ltd (DIR 176 – Limited and controlled release of white clover genetically modified for increased condensed tannins), as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a limited and controlled release*’

No audits and no investigations were undertaken during the quarter.

During the October - December 2021 quarter the OGTR finalised an audit of PGG Wrightson Seeds Limited to review their quality assurance processes as part of the OGTR Low Level Presence Strategy.

The OGTR also undertook an audit of Total Livestock Genetics Pty Ltd and PTM Solutions Pty Ltd to review existing quality assurance procedures and their consideration of any SDN-1 dealings.

These audits of the industry are ongoing and will be reported in the annual report.

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*.

² Desktop inspection