**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 PC2 Laboratory  | 16 |
| **Total** |  | **8** |

 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*.