

Quarterly activities report for October – December 2019

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 **six GM plant field trial sites** (Table 1). The inspections comprised:

- Current field trial sites – Of the **nine** sites current in the quarter, **two** were inspected. The sites were in the ACT and were selected for routine announced inspections as they had not been previously inspected.
- Post-harvest field trial sites – Of the **42** sites subject to post-harvest monitoring in the quarter, **four** were inspected. The sites were in the ACT and were selected for routine announced inspections. Two of the sites had not been previously inspected.

Table 1 – Summary of inspection activities of GM crop field trials for the October – December 2019 quarter.

Licence holder	Licence Number	GM Crop	Site location (crop status ¹)
CSIRO	DIR 151	Wheat	ACT (2C, 4PH)

¹ C = current site, PH = post-harvest site.

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

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

Table 2 – Summary of organisations and facility types that the OGTR inspected for the October – December 2019 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Deakin University	PC1 Facility	1
	PC2 Aquatic	2
Garvan Institute of Medical Research	PC2 Laboratory	2
	PC2 Aquatic	3
Griffith University	PC2 Animal	2
	PC2 Laboratory	9
	PC3 Laboratory	1
OMIC Australia Pty Ltd	PC2 Laboratory	1
Royal North Shore Hospital	PC2 Laboratory	6
Swinburne University of Technology	PC2 Laboratory	5
St Vincent's Hospital Sydney Limited	PC2 Laboratory	3
The Florey Institute of Neuroscience and Mental Health	PC2 Laboratory	6
Translational Research Institute Pty Ltd	PC2 Laboratory	3
	PC3 Laboratory	1
Total		45

Table 3 – Summary of inspection activities for DNIR licences for the October – December 2019 quarter.

Licence holder	Licence number
Griffith University	DNIR 535

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. The objective is to determine if licence conditions can be, and are being, effectively implemented.

During the October – December 2019 quarter the OGTR continued its program of Practice Reviews, undertaking meetings with:

- University of Queensland (DIR 169 – Limited and controlled release of microalgae genetically modified for increased production of fatty acids), as part of the practice review into the '*Preparedness of accredited organisations to undertake a limited and controlled release*';
- IQVIA RDS Pty Ltd (DNIR 601 – Clinical trial for BacTRL-IL-12 Phase 1 Trial in Humans with Various Cancers) as part of the practice review into the '*Preparedness of accredited organisations to undertake a dealing not involving an intentional release*'
- Griffith University (DNIR 579 – Investigating the mode of action of novel drug leads against *Giardia duodenalis*) as part of the practice review into the '*Preparedness of accredited organisations to undertake a dealing not involving an intentional release*'
- Medpace Australia Pty Ltd (DNIR 599 – A Phase 3, Open-Label, Randomized, Parallel Group Study to Evaluate the Efficacy and Safety of Intrapleural Administration of Adenovirus-Delivered Interferon Alpha-2b (rAd-IFN) in Combination with Celecoxib and Gemcitabine in Patients with Malignant Pleural Mesothelioma) as part of the practice review into the '*Preparedness of accredited organisations to undertake a dealing not involving an intentional release*'

Other activities

Monitoring and Compliance staff presented at the Australasian Society for Stem Cell Research – Australasian Gene and Cell Therapy Society – International Society Cell and Gene Therapy Australian and New Zealand Region 2019 Joint Scientific Meeting (Brisbane), as well as attending the 9th Annual Association of Biosafety for Australia & New Zealand Conference (Melbourne), and the Global Community Bio Summit 3.0 in Boston USA (11-13 October).

Monitoring and Compliance Findings

Findings from routine monitoring, auditing and investigations, and related enforcement activities, will be provided in the Regulator's Annual Report in accordance with section 136 of the *Gene Technology Act 2000*.