

Quarterly activities report for January – March 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 **5 GM plant field trial sites (Table 1)** and **1 GM Clinical trial site (Table 2)**. The inspections comprised:

- Current field trial sites – Of the **10** sites current in the quarter, **three** were inspected. Sites in the Shires of Toowoomba and the Lockyer Valley were visited by OGTR and were selected for both routine announced and unannounced inspections to assess compliance with licence conditions;
- Post-harvest field trial sites – Of the **47** sites subject to post-harvest monitoring in the quarter, **two** were inspected. The sites were at Toowoomba and Lockyer Valley and were selected for routine announced inspections; and
- One clinical trial.

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

Licence holder	Licence Number	GM Crop	Site location (crop status ¹)
Monsanto Australia Limited	DIR 147	Cotton	Toowoomba (1C)
The University of Queensland	DIR 153	Sorghum	Lockyer Valley (1C, 1PH) Toowoomba (1C)
Queensland University of Technology	DIR109	Banana	Innisfail (1PH)

Table 2 – Summary of inspection activities of Clinical Trials for the January – March 2019 quarter.

Licence holder	Licence number
Clinical Network Services Pty Ltd	DIR 144

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 **seven** organisations holding certified facilities (**Table 2**) and three undertaking DNIR licences (**Table 3**).

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

Organisation	Physical Containment (PC) level	Number of facilities monitored
University of Tasmania	PC2 Laboratory	6
	PC2 Animal	3
	PC2 Constant temperature	1
	PC2 Plant	4
	PC2 Aquatic	1
	PC2 Invertebrate	1
James Cook University	PC3	1
	PC2 Animal	2
	PC2 Laboratory	2
Australian Institute of Marine Science	PC2 Laboratory	2
Hudson Institute of Medical Science	PC2 Laboratory	3
Monash University	PC2 Laboratory	2
	PC2 Animal	1
	PC2 Aquatic	1
The Walter and Eliza Hall Institute of Medical Research	PC2 Laboratory	5
	PC1 Laboratory	3
CSIRO	PC2 Laboratory	1
Total		39

Table 3 – Summary of inspection activities for DNIR licences for the January – March 2019 quarter.

Licence holder	Licence number
James Cook University	DNIR 576
Monash University	DNIR 551
The Walter and Eliza Hall Institute of Medical Research	DNIR 572

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 January – March 2019 quarter the OGTR continued its program of Practice Reviews and visited:

- PSI-CRO Australia Pty Ltd proposed clinical trial for DNIR 577 as part of the practice review into effective measures for the planning for a licensed dealing not involving an intentional release.
- University of Queensland proposed trial for DIR-167 to determine if proposed containment measures could be effectively implemented.
- Janssen Cilag Pty Ltd proposed clinical trial for DNIR 588 as part of the practice review into effective measures for the planning for a licensed dealing not involving an intentional release.

Other activities

Monitoring and Compliance staff also undertook the following additional activities:

- Assisted the Contained Dealings Evaluation Branch with the re-certification of two PC3 facilities and one PC2 Large Scale Facility.
- Meeting with BioQuisitive Ltd, Alpha Space Pty Ltd, Gen Space (USA) and The University of Melbourne, discussed a proposed International Biosafety Manual for the DIY Biosafety Community.

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*.