

## Quarterly activities report for April – June 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 **6 GM plant field trial sites** (Table 1). The inspections comprised:

- Current field trial sites – Of the **10** sites current in the quarter, **four** were inspected. Sites in the Shires of Kimberley, Litchfield and the Lockyer Valley were visited by OGTR and were selected for routine announced inspections to assess compliance with licence conditions. The DIR 146 and DIR 147 sites had not been previously inspected.
- Post-harvest field trial sites – Of the **47** sites subject to post-harvest monitoring in the quarter, **two** were inspected. The sites were in the Kimberley and Lockyer Valley shires and were selected for routine announced inspections. The DIR-147 site had not been previously inspected.

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

Licence holder	Licence Number	GM Crop	Site location (crop status <sup>1</sup> )
Queensland University of Technology	DIR146	Banana	Litchfield (2C)
Monsanto Australia Limited	DIR 147	Cotton	Kimberley (1C, 1PH)
The University of Queensland	DIR 153	Sorghum	Lockyer Valley (1C, 1PH)

<sup>1</sup> 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 **six** organisations holding certified facilities (**Table 2**) and two undertaking DNIR licences (**Table 3**).

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

Organisation	Physical Containment (PC) level	Number of facilities monitored
University of Melbourne	PC2 Laboratory	3
	PC2 Animal	1
Sylvan Scientific	PC3 Laboratory	1
QIMR Berghofer Medical Research Institute	PC2 Laboratory	1
	PC2 Animal	2
Translational Research Institute	PC2 Laboratory	2
	PC2 Animal	2
CSIRO	PC2 Large Scale Facility	1
Menzies School of Health Research	PC3 Laboratory	1
<b>Total</b>		<b>14</b>

Table 3 – Summary of inspection activities for DNIR licences for the April – June 2019 quarter.

Licence holder	Licence number
University of Melbourne	DNIR 558
	DNIR 589
QIMR Berghofer Medical Research Institute	DNIR 554
	DNIR 591

### 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 April – June 2019 quarter the OGTR continued its program of Practice Reviews, undertaking meetings with:

- University of Melbourne (DIR-165 – limited and controlled release of GM wheat) as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a limited and controlled release*’;
- The University of Queensland (DIR-159 - Limited and controlled release of insect-specific viruses against infection in farmed crocodiles) as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a limited and controlled release*’; and
- Clinical Network Services Pty Ltd (DNIR-580 – clinical trial for a GM influenza vaccine) and Merck Sharp & Dohme (Australia) Pty Ltd (DNIR-594 – clinical trial for a GM cytomegalovirus vaccine) as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a dealing not involving an intentional release*’.
- BASF (commercial release cotton and canola) as part of the Post Release Review into the ‘*Oversight of commercially approved GM crops in Australia*’.

### **Other activities**

Monitoring and Compliance staff also undertook the following additional activities:

- Capacity building activities, to provide guidance and build regulatory understanding with Biofoundry Ltd (Sydney) and BioQusitive (Melbourne).
- Meeting with BioQusitive Ltd (Melbourne) and members of the Gene Technology Ethics and Community Consultative Committee to discuss the current state of Community Science in Australia.
- Attended a meeting with the Gene Technology Regulator (Dr Raj Bhula), Chief Medical Officer (Prof Brendan Murphy) and the Chief Veterinary Officer (Dr Mark Schipp) at the CSIRO Australian Animal Health Laboratory (Geelong).
- Engaged in continuing professional education at the Global Health Security Conference 2019 (Sydney).

### **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*.