

## Quarterly activities report for July – September 2018

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

- Current field trial sites – Of the **16** sites current in the quarter, **three** were inspected. Sites in the City of Marion and Moreton Bay had never been visited before by OGTR and were selected for routine announced inspections to assess compliance with licence conditions.
- Post-harvest field trial sites – Of the **48** sites subject to post-harvest monitoring in the quarter, **12** were inspected. A number of sites at Moreton Bay and Narrabri were selected for routine announced inspections due to the fact that they had not been previously inspected.

Table 1 – Summary of inspection activities of GM crop field trials for the July – September 2018 quarter.

Licence holder	Licence Number	GM Crop	Site location (crop status <sup>1</sup> )
CSIRO	DIR-115	Cotton	Narrabri (1PH)
	DIR-136	Cotton	Narrabri (1PH)
Department of Economic Development, Jobs, Transport and Resources	DIR-142	Wheat	Horsham (1PH)
Monsanto Australia Limited	DIR-147	Cotton	Narrabri (1PH)
Sugar Research Australia Limited	DIR-129	Sugarcane	Moreton Bay (1C), (3PH)
The University of Adelaide	DIR-128	Wheat & Barley	City of Marion (1C), (5PH)
	DIR-152	Wheat	City of Marion (1C)

<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 **11** organisations holding certified facilities (**Table 2**) and **one** undertaking DNIR licences (**Table 3**).

Table 2 – Summary of organisations and facility types that the OGTR inspected for the July – September 2018 quarter.

Organisation	Physical Containment (PC) level	Number of facilities monitored
Australian Catholic University	PC2 Laboratory	1
Centre for Eye Research Australia Ltd	PC1 Facility	1
	PC2 Laboratory	1
Federation University Australia	PC1 Facility	1
	PC2 Laboratory	1
Macfarlane Burnet Institute for Medical Research and Public Health <sup>2</sup>	PC3 Laboratory	1
Seqirus Pty Ltd <sup>2</sup>	PC2 Large Scale	1
Sugar Research Australia Limited	PC2 Laboratory	2
Sunshine Coast Health Institute	PC2 Laboratory	3
The University of Adelaide	PC2 Animal	2
	PC2 Aquatic	1
	PC2 Laboratory	1
	PC2 Plant	1
University of Newcastle	PC2 Animal	3
	PC2 Laboratory	7
University of the Sunshine Coast	PC2 Laboratory	1
Westmead Institute for Medical Research	PC2 Animal	1
	PC2 Laboratory	6
<b>Total</b>		<b>35</b>

<sup>2</sup> Two facilities were subject to joint inspections with the Contained Dealing Section for re-certification

Table 3 – Summary of inspection activities for DNIR licences and other contained instruments for the July – September 2018 quarter.

<b>Licence holder</b>	<b>Instrument Identifier</b>
Westmead Institute for Medical Research	DNIR-011 DNIR-303 DNIR-401 DNIR-422
Daniels Health (NSW)	TSD-011 <sup>3</sup>

### **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 July – September 2018 quarter OGTR continued its program of Practice Reviews and visited Bioproperties Pty Ltd proposed trial site for DIR-154 and The Department of Economic Development, Jobs, Transport and Resources (Victoria) proposed trial site for DIR-160 as part of the Practice Review into *Preparedness of accredited organisations to undertake a limited and controlled release*.

One visit to Monsanto Australia Limited was conducted under the Practice Review into *Post Release Review Measures for Commercial Release DIR Licences*, as part of OGTR’s long-term monitoring of commercial GM crops after their approval.

Auditing was conducted in Victoria in order to review seed breeding quality assurance processes as part of the OGTR Low Level Presence Strategy. These audits of the industry are ongoing and will be reported in the Regulator’s Annual Report.

### **Other activities**

Monitoring and Compliance staff also undertook the following additional activities:

- Engaged in continuing professional education and stakeholder engagement activities at the Australian Seeds Federation Conference held in Melbourne from 21 – 23 August 2018 and the Association of Biosafety for Australia & New Zealand ‘Practical Biocontainment Practices’ in Geelong on 13 – 14 September 2018; and

Undertook capacity building activities, to provide guidance and build regulatory understanding, with Biofoundry Ltd in NSW.

<sup>3</sup> TSD-011 refers to alternate transport, storage & disposal requirements issued to Daniels Health under regulation 13(3)(b)(ii) of the *Gene Technology Regulations 2001*

**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*.