

Quarterly activities report for July – September 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 **four GM plant field trial sites** (Table 1). The inspections comprised:

- Current field trial sites – Of the **nine** sites current in the quarter, **one** was inspected. The DIR-165 site had not been previously been inspected and was chosen for a practice review.
- Post-harvest field trial sites – Of the **47** sites subject to post-harvest monitoring in the quarter, **three** were inspected. The sites were in the Narrabri shire and were selected for routine announced inspections. The DIR-136 and DIR-147 sites had not been previously inspected.

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

Licence holder	Licence Number	GM Crop	Site location (crop status ¹)
CSIRO	DIR-136	Cotton	Narrabri (1 PH)
Monsanto Australia Limited	DIR-147	Cotton	Narrabri (2 PH)
The University of Melbourne	DIR-165	Wheat	Greater Shepparton (1C)

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 **15** organisations holding certified facilities (**Table 2**) and **five** undertaking DNIR licences (**Table 3**).

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

Organisation	Physical Containment (PC) level	Number of facilities monitored
Intertek Testing Services (Australia) Pty Ltd	PC2 Plant	1
University of South Australia	PC2 Laboratory	1
	PC2 Invertebrate	1
	PC2 Aquatic	1
University of New South Wales	PC2 Animal	1
Central Adelaide Local Health Network	PC2 Laboratory	2
CMAX Clinical Research Pty Ltd	PC2 Laboratory	1
South Australian Health and Medical Research Institute	PC2 Animal	5
	PC2 Large Grazing Animal	7
Planet Innovation	PC2 Laboratory	1
Harry Perkins Institute of Medical Research	PC2 Laboratory	3
Curtin University	PC2 Laboratory	3
Ralph and Patricia Sarich Neuroscience Research Institute	PC2 Laboratory	3
Department of Agriculture and Fisheries	PC2 Plant	1
Intervet Australia Pty Ltd	PC2 Laboratory	1
	PC2 Large Scale	1
The University of Melbourne	PC2 Large Grazing Animal	1
Queensland University of Technology	PC2 Laboratory	2
	PC2 Plant	2
CSIRO	PC2 Plant	1

Organisation	Physical Containment (PC) level	Number of facilities monitored
Total		39

Table 3 – Summary of inspection activities for DNIR licences for the July – September 2019 quarter.

Licence holder	Licence number
University of South Australia	DNIR-578
CMAX Clinical Research Pty Ltd	DNIR-564
Harry Perkins Institute of Medical Research	DNIR-091 DNIR-208 DNIR-487
Curtin University	DNIR-563
Intervet Australia Pty Ltd	DNIR-301

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 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*’;
- Queensland University of Technology (DIR 166 - Limited and controlled release of genetically modified chickpea genetically modified for drought and other environmental stress tolerance);
- Merck Sharp & Dohme (Australia) Pty Ltd (DNIR-594 – clinical trial for a GM cytomegalovirus vaccine); Ridley Corporation Limited (DNIR-596 - Importation of US corn for further processing into stockfeed); Inghams Group Limited (DNIR-595 - Importation of US corn for further processing into poultry feed); BioMarin Pharmaceutical Australia Ltd (DNIR-600 - Studies to evaluate the efficacy and safety of BMN 270, an Adeno-Associated Virus vector-mediated gene transfer of human factor VIII in haemophilia A patients); GlaxoSmithKline Australia Pty Ltd (DNIR-587 - Clinical trials with Respiratory Syncytial Virus (RSV) investigational vaccine ChAd155-RSV) as part of the practice review into the ‘*Preparedness of accredited organisations to undertake a dealing not involving an intentional release*’ and
- University of New South Wales – as part of the practice review into ‘*Facility Structure and Maintenance*’.

Other activities

Monitoring and Compliance staff took no additional activities.

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*.