Published on *The National Law Review* https://natlawreview.com

2016-2017 Technical Review of Australian Gene Technology Regulations 2001

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UPDATE: OGTR Releases Guidelines on Organisms Containing "Gene Drives"

The deadline for submissions on the discussion paper prepared by the Office of the ***Australian Gene Technology Regulator (OGTR)*** concerning its review of the Gene Technology Regulations closed on 16 December 2016, and submissions received by the Regulator have yet to be made publicly available.

However, the ***Office of the Gene Technology Regulator (OGTR)*** has now issued guidelines for ***Institutional Biosafety Committees (IBCs)*** and researchers on the regulatory requirements for organisms containing engineered 'gene drives' following the discussion paper consultation which revealed that some stakeholders were not aware organisms genetically modified to contain 'gene drives' are GMOs. The guidelines reflect the current requirements under the ***Gene Technology Act 2000 (Act)*** and will be amended to reflect any changes that are ultimately made.

The OGTR considers 'gene drives' to be "genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance". If gene technology is used to introduce or create a gene drive in an organism, the resulting organism will be a GMO and subject to regulation under the Act.

Research into gene drives is not new – the application of selfish homing endonuclease genes to manipulate natural populations was proposed more than a decade ago.[1] But recent developments in the field of genome editing, in particular, the discovery of the CRISPR-Cas9 system, have rapidly expanded the potential applications of gene drives. In 2015, for example, CRISPR-Cas9 gene drives were employed to ensure that genetically engineered mosquitos would pass on engineered genes to substantially all of their offspring[2] With technological advances outpacing policy development, it is timely that the OGTR provide guidance to organisations looking to conduct research into gene drives.

The OGTR provides the following guidance in relation to the regulation of gene drive research:

- There are currently no specific categories for gene drives in the Regulations.
- Generally, research involving genetically modified plants and animals containing engineered

gene drives in certified physical containment facilities will be classified as ‘notifiable low risk dealings’ (NLRDs). However, certain dealings with GMOs containing gene drives may require a licence from the Regulator (for example, if the introduced nucleic acid encodes a toxin or if the modification enables the organism to produce infectious agents).

- Any GMO with a functional engineered gene drive is considered to confer an advantage relative to the unmodified parent organism to survive, reproduce or otherwise contribute to the gene pool, and as such a minimum containment level of PC2 is required.

- IBCs must consider, among other matters, the suitability of the proposed containment facilities in assessing NLRDs. If necessary, the IBC may specify facilities at a higher containment level than the minimum requirements under the Regulations. Conversely, where there is evidence that the engineered gene drive system incorporates ‘fail safe’ mechanisms to limit potential spread in case of accidental release, those mechanisms can be taken into account for the purposes of stipulating physical containment requirements

The technical review of the Gene Technology Regulations includes consideration on how organisms containing engineered ‘gene drives’ should be regulated. Until completion of the review and any amendments to the Gene Technology Regulations are finalised, IBCs and researchers are encouraged to refer to the OGTR guidelines.

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[1] Burt, A. Site-specific selfish genes as tools for the control and genetic engineering of natural populations. *Proceedings of the Royal Society B: Biological Sciences* (2003) 270, 921-928.

[2] Gantz V.M. *at al*. Highly efficient Cas9-mediated gene drive for population modification of the malaria vector mosquito *Anopheles stephensi*. *Proceedings of the National Academy of Sciences of the USA* (2015) 112, E6736-E3743; Hammond A. *et al*. A CRISR-Cas9 gene drive system

targeting female reproduction in malaria mosquito vector *Anopheles gambiae*. *Nature Biotechnology* (2015) 34, 78-83.

National Law Review, Volume VII, Number 11