Australian Government
Department of Health
Office of the Gene Technology Regulator

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Guidance for IBCs:

Regulatory requirements for contained research with GMOs containing engineered gene drives

This document provides guidance for Institutional Biosafety Committees (IBCs) and researchers on the regulatory requirements for organisms containing engineered 'gene drives', including the physical containment (PC) level of facilities for notifiable low risk dealings (NLRDs).

Gene drives are genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance. Gene drives can only spread from sexually reproducing parents to their offspring.

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 *Gene Technology Act 2000*.

NLRD or licence?

Amendments to the Commonwealth Gene Technology Regulations 2001 commence on **8 October 2019**.

Under these amendments, contained dealings with **GMOs containing functional gene drives will require a Dealings Not involving Intentional Release (DNIR) licence** to be undertaken in contained facilities (**Schedule 3 3.1(r)**). Dealings with **viral vectors that can modify an organism to produce an engineered gene drive will also require a DNIR licence** (**Schedule 3 3.1(s)**).

Prior to commencement of these amendments, dealings with GM plants and GM animals containing engineered gene drives in certified physical containment facilities are generally classified as Notifiable Low Risk Dealings (NLRDs) [Schedule 3 Part 2.1 (a), (aa) or (b)], although dealings with some GMOs containing engineered gene drives may have required a licence, depending on the type of organism and the nature of the modification. For example, if the introduced nucleic acid encodes a toxin [Schedule 3 Part 3.1 (a), (b) or (c)], or if the modification enables the organism to produce infectious agents [Schedule 3 Part 3.1 (k)], a licence from the Regulator is required.

Under transitional provisions, such **dealings authorised as an NLRD prior to commencement** of these amendments, but which require a licence after commencement, **can continue as an NLRD until 8 October 2020**, before which time a licence must be obtained or the dealings ceased and the GMOs destroyed.

More information on the amendments is available on the Amendment Regulation Implementation page

'Advantage' and containment level for NLRDs

Research involving GM laboratory mice, rats, rabbits or guinea pigs in certified containment facilities is generally classified as an NLRD suitable for at least PC1 [**Schedule 3 Part 1.1 (a)**]. However this is not the case if the modification confers an advantage.

Any GMO with a functional engineered gene drive is considered to have an advantage (as defined in regulation 3) due to its enhanced ability to contribute to the gene pool, and a **minimum containment level of PC2** is required [**Schedule 3 Part 2.1 (aa)**].

IBC assessment of NLRDs (relevant to gene drives prior to commencement of amendments)

NLRDs must be assessed by an IBC before being conducted [**regulation 13**]. In assessing an NLRD proposal, an IBC must consider, among other matters, the suitability of the proposed containment facility for the particular activities proposed [**regulation 13B(a)(vii)**]. This allows an IBC to specify facilities at a higher containment level than the minimum dictated by the Regulations, or to specify a facility or facilities with particular attributes, should the IBC consider this is appropriate to ensure containment of the GMOs. If an IBC considers that a particular engineered gene drive-containing GMO needs more stringent containment than other GMOs of the same species, the **IBC should ensure that its record of assessment for the NLRD specifies appropriate containment facilities**.

Some engineered gene drive systems incorporate mechanisms to limit potential spread in case of accidental release, for example by separating components of the gene drive onto different chromosomes or targeting a synthetic gene sequence that only exists in a particular laboratory population of GMOs. If used, and there is evidence to support their effectiveness, such fail-safe mechanisms can be taken into account in considering physical containment requirements.

Assessment of containment for licence applications

The Regulator considers the suitability of containment options in preparing risk assessment and risk management plans (RARMPs) for licence applications. Applicants proposing work with GMOs containing engineered gene drives should address the suitability of proposed containment in their application. As noted above, the use of fail-safe mechanisms can be taken into account in considering appropriate physical containment. If used, such fail-safe mechanisms should be described in detail, and will be considered by the Regulator in the RARMP.

Further information

If in doubt about the appropriate classification or physical containment of proposed work with GMOs containing engineered gene drives, please contact the OGTR for specific advice (1800 181 030 or ogtr@health.gov.au).