CropLife Australia

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National Gene Drive Policy Guide

Consultation Draft

1. INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biologically based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, Australian and International companies and accordingly, CropLife advocates for policy positions that deliver whole of industry and national benefit. Our focus is, however, specifically on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability. Both of which are achieved through access to world-class technological innovation and products of the plant science sector.

CropLife welcomes the opportunity to comment on the draft National Gene Drive Policy Guide (the draft Guide) developed by the Department of Health and Aged Care. This document is a welcome development towards clarifying the application of the existing Australian regulatory framework to ensure the safe and effective use of gene drive technologies. We appreciate that this document directly addresses Recommendation 7b of the Third Review of the National Gene Technology Scheme (the Review). However, CropLife continues to express deep concern regarding the ongoing delays in implementing the remaining recommendations from the Review. CropLife is concerned these delays have created a chilling effect on investment and the longer it takes for us to get a future-oriented scheme in place, the further ahead our competitors for this investment from commercial sources will be.

We note that the regulatory requirements applicable to contained research activities with gene drives have already been clarified by the Office of the Gene Technology Regulator (OGTR) with the 2019 amendments to the Gene Technology Regulations.

While the draft Guide represents a key first step in developing policy guidelines for Australia, we suggest that greater clarity regarding the regulatory obligations is needed. Furthermore, we highlight the gene drive policy would benefit from including a more comprehensive selection of existing works on gene drives.

2. ENSURING CLARITY OF TEXT AND INCORPORATION OF EXISTING WORK

CropLife recognises the complexities of Genetically Modified Gene Drives (GMGDs) from both regulatory and technology perspectives. Therefore, general policy guides encompassing all aspects and outcomes are difficult to develop. However, we note that Australia does not need to and should not remain isolated from contemporary regulatory practice and discourse in policy development.

CropLife is concerned that the draft Guide does not draw widely enough on existing frameworks and literature. Providing this additional context would help with understanding the technology and also offer assurances that Australia's regulatory discussion is progressing in line with modern global science-based regulatory trends. Opportunities to

provide additional context can be observed throughout the draft Guide but we have highlighted some of the most significant omissions, including technical and regulatory works. Moreover, we have also suggested changes to improve flow and consistency. We would also recommend reviewing the weblinks provided throughout as they often do not provide directly relevant resources or clear guidance.

In addition, CropLife Australia suggests a stronger discussion of how the draft Guide might address Recommendations 23 – 27 of the Review. This should include acknowledgement of how GMGDs may address the disadvantages of Australia's First Nations People be included.

Section 1:

Although section 1 provides an overview of GMGDs and their regulation, it fails to adequately incorporate work detailing both the high-level understanding and the low-level nuance not captured. While lower-level details may not assist the entire target audience, they should be identifiable.

With technological developments within this area moving so quickly, the inclusion of functional specifics would quickly date any policy document; however, the inclusion of high-level behavioural aspects of GMGDs is needed. To aid this, we would recommend the expansion of 'What are gene drives?' to include behavioural aspects that impact the likelihood and speed of GMGD establishment within the target population. This might include discussion of release rates, population thresholds, self-limiting drives, the evolution of resistance, and the cost of genetic payloads. Moreover, this subsection should precede the "Genetically modified gene drive (GM gene drive) organisms" subsection. This GMGD subsection should provide specific information about potential applications in Australia. For example, the case studies provided as extrinsic material online[1] could be incorporated here.

The subsection "Regulation of gene drive organisms" only addresses the regulatory scheme administered by the OGTR despite previously setting the scene that a "multitude of administrative and legislative processes" potentially apply. An overview of this should be provided here, e.g. the 2017 Discussion Paper of the Australian Academy of Science[2] provides a clearer explanation of what and why other legislative provisions may apply.

As an aside, accuracy is needed in the terminology used, e.g. "The term gene drive is used to describe organisms which have been genetically modified…". A gene drive system is

1 The Department of Health and Aged Care (2023) Hypothetical gene drive environmental release case studies. Accessed 27 February 2024. https://www.genetechnology.gov.au/resources/publications/hypothetical-gene-drive-environmental-release-case-studies.

2 Australian Academy of Science (2017) Synthetic Gene Drives in Australia: Implications of Emerging Technologies. Accessed 27 February 2024 https://www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies.

separate from the organism, with genetic modification required to generate a genetically modified organism containing an engineered (or synthetic) gene drive.

Section 1 also provides two figures with no title or explanation and a link to a general website for the National Gene Technology Scheme.

Section 3:

It is inaccurate to state that there "is currently no specific policy for guidance in the form of international standards or guidelines for the risk assessment of GM gene drive organisms".[3] There are numerous publications that provide guidance or recommendations on the matter, including:

- the 2021 WHO Guidance[4],
- the 2016 review conducted by the National Academies of Science, Engineering and Medicine (NASEM)[5], and
- a substantial body of work published by the gene drive research community[6,7,8].

These works address, inter alia, responsible technology development, environmental risk assessment, and governance frameworks. Also, international decisions have been made regarding gene drive research activities and risk assessment under the Convention on Biological Diversity (CBD), with a program of work currently in progress towards the development of additional guidance materials for risk assessment under the Cartagena Protocol on Biosafety to the CBD.

Section 4:

Section 4 could likely be merged, at least in part with section 3, and duplication removed, while retaining the content regarding a "pre-application meeting" and "figure 1" in Section 4. The section title does not appropriately reflect its content, and there are aspects that require further explanation. For example, in step 3 of Figure 1, it needs to be clear where responsibilities lie. According to the text in the document the proponent is responsible for extensive consultation, but this figure indicates that consultation is also undertaken by the OGTR. This figure also suggests that the OGTR will consider social license, as well as social,

3 The Department of Health and Aged Care (2023) Consultation Draft National Gene Drive Policy. Canberra: Commonwealth of Australia (Department of Health and Aged Care) CC BY 4.0. at page 7.

4 World Health Organization (2021) Guidance Framework for Testing of Genetically Modified Mosquitoes (2nd edition). Accessed 27 February 2024. https://www.who.int/publications/i/item/9789240025233.

5 National Academies of Science, Engineering and Medicine (NASEM) (2016). Gene drives on the horizon: advancing science, navigating uncertainty, and aligning research with public values. Washington DC: National Academies of Sciences, Engineering and Medicine.

6 Omar S. Akbari et al. (2015) Safeguarding gene drive experiments in the laboratory. *Science* 349,927-929. https://doi.org/10.1126/science.aac7932.

7 Kanya C. Long et al. (2020) Core commitments for field trials of gene drive organisms. *Science* 370,1417-1419 https://doi.org/10.1126/science.abd1908

8 Bier, E. Gene drives gaining speed (2022). *Nature Review Genetics* 23, 5–22. https://doi.org/10.1038/s41576-021-00386-0.

ethical and cultural considerations, and comparative benefits – these are new regulatory requirements that ostensibly go against recommendation 19 of the Review. We question the legal mandate, policy directives and legislative basis for these.

Figure numbering and explanations need to be reviewed. For example, this section has labelled the figure on page 10 as Figure 1, despite there being an uncaptioned inheritance figure(s) on page 3.

Section 5:

Section 5 would be improved by the inclusion of an item on "comparators", for the purpose of establishing that the concept of suitable/relevant comparators may be expanded (compared to previously released GMOs in Australia) to inform risk assessment for GMOs containing engineered gene drives. For example, for control of an insect vector of human disease, comparators could include the same species with a genetic background as similar as possible to the GMO, the target species/organism, and other disease vector/pest control systems.

Section 6:

The first paragraph of section 6 would be helpful earlier in the document, such as within the "Regulation of gene drives" section.

For the item "(xv) Comparative benefits relative to existing technologies", the word "technologies" could be replaced with "interventions". Where gene drives are intended to address a problem for which other interventions are already used, the proposed gene drive should be compared to these. However, an acknowledgement that circumstances exist where no comparable intervention exists is warranted.

The item "(xvii) Monitoring and surveillance post release" talks about two areas of monitoring – of the GMO itself and of efficacy, with the latter relevant to product performance and not within the remit of the GT Regulator. It would be helpful if this was clearer in the text.

The target audience would benefit from greater clarification for matters within the 'purview of the scheme'. The draft Guide does not provide context for how various pieces of information would be used or how the requirements of state / commonwealth / environmental / industry / etc bodies might be applied. As it currently stands, this document generally - but this section in particular - provides little clarity for proponents of the technology.

Section 7:

There are numerous frameworks, especially in the public health space, that can be drawn on in section 7. Perhaps one of the most relevant from an Australian perspective is the

deployment of *Wolbachia*-infected mosquitoes in northern Queensland.[9],[10] Although held by the OGTR (and numerous other regulatory agencies) not to be genetically modified, this technology does have similarities with current gene drive technologies in that the objective was to drive *Wolbachia* through a target population via perturbing of sexual reproduction. It would be helpful for a proponent of gene drive to know if this, or any other engagement model, would be applicable.

3. PROVIDING REGULATORY CLARITY

CropLife recognises that any guidance in this area will be far from exhaustive. However, at this early stage, there are limited applications currently being proposed for Australia. Those that have been proposed are captured well in the case examples, but these provide little clarity on the applicable regulatory frameworks. Through the Gene Technology Minister's Meeting, the Department of Health is uniquely qualified to engage with both commonwealth and state authorities.

In addition, and contrary to Recommendation 19 of the Review, the draft Guide introduces new regulatory elements for which little clarity is provided – i.e. the responsible authorities, relevant guidance (legislation), application and thresholds for the new concepts of social licence, public good and comparative benefits are not provided. While these concepts have consistency with relevant international guidance, e.g. the stakeholder and community engagement recommendations of the WHO Guidance Framework for Testing of Genetically Modified Mosquitoes, and with real-world experience in Australia with the engagement undertaken prior to deployment of *Wolbachia*-infected mosquitoes, they are new GMO regulatory elements that require greater explanation, as well as justification for the departure from Recommendation 19. While these will differ greatly based on the specifics of any given proposed deployment of a GMO containing an engineered gene drive, non-exhaustive worked examples could be provided.

The draft Guide would benefit greatly from highlighting the distinction between actual regulatory requirements and what is considered best practice, with reference to appropriate frameworks. At present it is unclear which is which. This is particularly problematic in sections 3 and 7.

It should also be acknowledged that presently the deployment of GMGDs would be a matter of public policy rather than commercial interest. As such, these interventions would be

9 De Barro PJ et al. (2011) The proposed release of the yellow fever mosquito, *Aedes aegypti* containing a naturally occurring strain of *Wolbachia pipientis*, a question of regulatory responsibility. *Journal fur Verbraucherschutz und Lebensmittelsicherheit* 6(S1) 33-40. https://doi.org/DOI 10.1007/s00003-011-0671-x

10 O'Neill SL et al. (2019) Scaled deployment of Wolbachia to protect the community from dengue and other *Aedes* transmitted arboviruses. *Gates Open Research* 2019, 2:36. https://doi.org/10.12688/gatesopenres.12844.3.

expected to rely on government investment and philanthropy, and likely would be driven by Departments of Health or Environment.

Section 2:

Section 2 states that the purpose of the draft Guide is to provide clear guidance, but we are concerned that this has not been achieved. Specifically, the necessary information for "proponents to ensure that they have considered the complete range of risk considerations; and all relevant laws that may be activated at State, territory, or Commonwealth level" (emphasis added) is not provided and we would welcome such clarity. Further, this section incorrectly states that the document "does not impose any additional regulatory requirements". It is our interpretation that establishing "social license", "public good" and "comparative benefits" are new regulatory requirements for a GMO.

Section 3:

CropLife is concerned that the draft Guide will either impose new regulatory requirements or a quasi-regulatory burden. This is evident in the beginning of subsection 3.1, which states GMGDs "should constitute a clear public good". Moreover, the section raises many unaddressed questions – what is the measure of "a clear public good objective" and who will assess if a "case is established"? Apart from the fact that it is unlikely that a developer would invest in and seek to release a technology that did not have an intended beneficial outcome, the vague list of entities that "may be able to assist" with this does not constitute guidance. The inclusion of "Non-governmental organisations" in this list needs to be balanced by the inclusion of the scientific community. It is also unclear which regulatory agency would evaluate public good. It should be noted that "benefits" are not within the OGTR regulatory remit.

CropLife is also concerned that Subsection 3.1 limits GMGDs to "pest control, disease control/public health or species conservation". This is an unnecessary limitation on the application of the technology that will only serve to limit the life of the document.

It is also unclear what the distinction is between "public good" in subsection 3.1 and the concepts of establishing social licence (subsection 3.5, section 7) or comparative benefits in (section 6 subsection (xv), and section 7). These concepts appear to represent new regulatory requirements but their legislative authority and interaction with existing frameworks are unclear. The only example provided, the Northern Territory (NT) Social Outcomes Framework, is directed towards NT government departments. While the outcomes and indicators listed in the NT framework are commendable, it is difficult to understand the application of this framework except on the most superficial level.

Section 7:

Although social licence and public consultation are critical in many regulatory frameworks, as noted above, the concepts and their application are impossible to discern within the draft Guide.

In addition, this section likely needs greater consideration of how the opinions of affected and non-affected individuals are weighed. Could a GMGD seeking to eradicate cane toads in the Kimberley be blocked by the residents of Hobart? Could a mosquito GMGD targeting Murray Valley encephalitis in Melbourne be shelved due to vocal opposition from Brisbane residents? Obviously, there is no easy answer for this and will relate closely to project-specifics. However, greater discussion of the issues with reference to existing literature would be beneficial.

4. CONCLUSION

CropLife and its members are committed to supporting Australian farmers by ensuring they can access the innovations, technologies, tools and products they need to maintain sustainable and profitable farming practices. As highlighted throughout the literature, GMGDs are potentially a powerful tool for not only farming but also conservation and public health.

CropLife Australia members have long-term experience regarding the environmental release of biotech crops and the requirements of the Australian regulatory scheme administered by the OGTR and other authorities where applicable. We recognise that the environmental release of genetically modified organisms (GMOs) containing engineered gene drives raises broader considerations due to their potential, depending on the type of drive system used and distribution of the target population, to move across jurisdictional borders. The draft Guide states an intention to provide clarity in this regard, but it merely flags that a multitude of administrative and legislative processes already exist – and the onus is on the technology developer to figure out what may apply and the responsible authorities. This is a missed opportunity by the authors to provide a genuinely useful document.

Given the issues described above, as it currently stands it is difficult to see how the Consultation Draft Nation Gene Drive Policy Guide is useful for proponents and developers of gene drive technology in Australia. We suggest that this document be revised substantially with greater consultation, and review of relevant resources undertaken to demonstrate how existing administrative and legislative processes might be applied to a handful of examples (such as those in the case studies).