CONVENTION ON BIOLOGICAL DIVERSITY (CBD)
NOTIFICATION 2019-009

Submission of information for paragraph 10 of decision CP-9/13 – Risk assessment and risk management

Australian Government

CARTAGENA PROTOCOL ON BIOSAFETY

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Submission of information for paragraph 10 of decision CP-9/13 – Risk assessment and risk management

Australian Submission, March 2019

Australia is responding to the invitation to Parties to the Cartagena Protocol on Biosafety, other Governments, indigenous peoples and local communities, and relevant organisations, to submit information related to the following:

- Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so;
- Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish; and
- Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

Australia thanks the Secretariat of the Convention on Biological Diversity for this opportunity.

Gene Technology Regulation in Australia

The Australian Government supports science-based decision making. The object of Australia's National Gene Technology Scheme (Scheme), defined in the *Gene Technology Act 2000* (the Act)[1], is to:

> "protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs [genetically modified organisms[2]]."

The Act provides for an independent statutory office holder, the Gene Technology Regulator (Regulator). All dealings[3] with GMOs are prohibited unless authorised under the Act. The Regulator's decisions on authorisations are underpinned by sound science and rigorous risk analysis.

Licences are required for GMO dealings involving intentional release of a GMO into the environment, and for particular GMO dealings in containment facilities. Each application for a licence to work with a GMO is subject to a comprehensive, science-based, case-by-case analysis process which, for dealings involving an intentional release of a GMO into the environment, includes public consultation.

While the Regulator is responsible for decisions on activities with live GMOs, Australian product regulators administer other laws that may be applicable to GMOs or their products.

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[1] https://www.legislation.gov.au/Latest/C2016C00189

[2] equivalent to living modified organisms

[3] "Dealing" in relation to a GMO is defined under Section 10 of the *Gene Technology Act 2000*; it includes, but is not limited to the following: to conduct experiments with a GMO; to make, develop, produce or manufacture a GMO; and to import, transport and dispose of a GMO

For example, while growing a GM plant in the field is subject to regulation under the Act, use of the GM plant material in commercially available food requires a pre-market safety assessment by Food Standards Australia New Zealand. Other product regulators include those responsible for human medicines, animal medicines and agricultural chemicals, industrial chemicals and biosecurity of imports. In addition, the Environment Minister administers the *Environment Protection and Biodiversity Conservation Act 1999* which provides for the protection of the environment, with an emphasis on matters of national environmental significance. The Regulator consults with the Environment Minister and the product regulators when assessing a GMO for environmental release.

Specifically in regard to the request for information pertaining to risk assessment of living modified organisms containing gene drives and living modified fish, and noting the objective of the Cartagena Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms and that these dealings may have adverse effects, Australia provides the following:

- **Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so**

Engineered gene drives

In Australia, organisms carrying engineered gene drives are regulated as GMOs under the Act, noting there have been no applications for release of an engineered gene drive GMO into the environment in Australia.

The Regulator has issued specific guidance on contained research with GMOs containing engineered gene drives[4]. This includes guidance on the regulatory requirements, for example, whether a licence is required; and the level of physical containment (PC) in which a dealing must be undertaken.

Both regulatory requirements and the level of containment required are dependent on the type of organism and the nature of the genetic modification. For example, dealings with GMOs containing engineered gene drives require authorisation via a licence from the Regulator if the introduced nucleic acid encodes a toxin, or if the modification enables the organism to produce infectious agents. Contained activities with a GMO containing a functional engineered gene drive must be undertaken in a minimum of PC2[5] containment.

If an application proposing environmental release of engineered gene drive GMOs were received, the Regulator would undertake a thorough risk assessment, following the principles and approaches outlined in OGTR's Risk Analysis Framework (detailed further below). The Risk Analysis Framework and the Australian gene technology legislation reflect the principles and methodology outlined in Annex III to the Cartagena Protocol. The Act mandates preparation of a Risk Assessment and Risk Management Plan (RARMP) in relation to dealings proposed to be authorised before the Regulator decides whether to issue a licence. A RARMP includes critical assessment of data provided by the applicant, together with a thorough review of other relevant national and international scientific literature. The risk

[4] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/$File/OGTR%20guidance%20on%20gene%20drives.pdf

[5] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc2-1

assessment takes account of risks to people and the environment posed by the dealings; the risk management plan determines how those risks can be managed.

In preparing a RARMP, the Regulator consults other relevant Australian agencies as noted above. The Regulator must not issue a licence unless satisfied that any risks posed by the dealings are able to be managed so as to protect the health and safety of people and the environment.

Australia considers that risk assessment approaches for non-LMO biological control agents and exotic species may be informative for risk assessment of organisms containing engineered gene drives. For example, risk assessment guidance and processes used for assessing risks involved in releasing wild type biological control agents designed to eliminate or eradicate an invasive alien species would have similarities to the assessment of an engineered gene drive organism for population control.

In addition, Australia considers that the key concepts for environmental risk assessment of LMOs articulated by the OECD[6] remain relevant and valid for framing risk assessments of new types of LMOs, including organisms with engineered gene drives. In particular, the key conceptual framework of considering the biology of the unmodified species (e.g. the wild type), the nature of the introduced trait (e.g. the genetic modification and the resultant genotype and phenotype), the receiving environment, and the interaction between these three aspects, as well as the intended use of the LMO. The 2006 OECD document 'Points to Consider for Consensus Documents on the Biology of Cultivated Plants'[7], although written for plants specifically, nevertheless also points to key general attributes of organisms that are important for risk assessment and may be applied to other organisms. For example, understanding reproductive biology to inform potential for gene flow within and between species, aspects of the biology of the organism that enable it to survive, persist or spread in particular environments, and interactions of the organism with other organisms. It may also be noted that the OECD has recently also published biology documents for Atlantic Salmon[8] and for the mosquito *Aedes aegypti*[9].

Genetically modified fish

The Regulator has issued Guidelines specific for PC2 aquatic facilities[10] in which authorised GMO dealings, including with genetically modified (GM) fish, may be undertaken. Various low-risk dealings with GM fish have been authorised as notifiable low risk dealings (NLRDs) that could be undertaken in appropriate certified facilities. NLRDs are activities with GMOs undertaken in containment that have been assessed as posing low risk to the health and safety of people and the environment, provided certain standard risk management conditions are met.

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[6] Safety Considerations for Biotechnology: Scale-up of Crop Plants, http://www.oecd.org/chemicalsafety/biotrack/1958527.pdf

[7] ENV/JM/MONO(2006)1, https://www.oecd.org/env/ehs/biotrack/46815838.pdf

[8] http://www.oecd.org/publications/safety-assessment-of-transgenic-organisms-in-the-environment-volume-7-9789264279728-en.htm

[9] http://www.oecd.org/publications/safety-assessment-of-transgenic-organisms-in-the-environment-volume-8-9789264302235-en.htm

[10] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/PC2AqV3.1-toc/$FILE/PC2AqV3.1.pdf

As for engineered gene drives, if an application for a licence authorising an environmental release of a GM fish were received, the Regulator would undertake case-by-case assessment, including preparation of a RARMP specific to the proposed dealings, as detailed above. While such an assessment has not been completed in relation to GM fish, experience gained through Australia's assessment of exotic fish species prior to proposed introduction into the Australian environment would be informative. Likewise, information on adverse effects from the introduction of non-native species to Australia could inform the identification of possible pathways to harm and the evaluation of risk mitigation measures.

- **Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish**

Australia has a strong legislative and regulatory framework in place in regard to modern biotechnology, including engineered gene drives and GM fish. The Act and the Risk Analysis Framework are framed broadly, and the principles articulated in the Risk Analysis Framework are broad enough to be applicable for the risk assessment of GM fish and of engineered gene drive GMOs.

As articulated in Australia's submission on CBD Notification 2017-035, Australia does not support the development of separate guidance documents for the risk assessment of specific types of LMOs under the Cartagena Protocol on Biosafety. Australia supports developing a single, practical and generic guidance document based on current risk assessment practices that could be used to assess all types of LMOs. Well-designed generic risk analysis guidance should allow for the identification and assessment of all plausible pathways to actual harm that could reasonably be expected to result from the intentional environmental release of LMOs. Risk assessment guidance and processes used for assessing the risks involved in releasing wild type biological control or bioremediation agents, control of invasive alien species or indigenous use of threatened species may be able to be adapted to LMOs.

Australia's recent Third Review of the National Gene Technology Scheme[11] considered what regulatory oversight is appropriate for genetically modified biological control agents, including those with engineered gene drives. The review recommended clarifying, and where necessary strengthening, the mechanisms for regulating the broader environmental release of GMOs and environmental release of GM gene drive organisms.

- **Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives**

Australia's approach to risk analysis of GMOs is detailed in the Regulator's *Risk Analysis Framework*[12]. Within the context of the Act, this Framework ensures:

- provision of a guide to the current rationale and approach to risk analysis;
- a consistent and rigorous risk analysis approach to evaluating licence applications and making decisions about other classes of GMO dealings; and
- transparency on the use of risk analysis to support decision making.

This document is consistent with Annex III of the Cartagena Protocol, which provides broad guidance on how to perform risk assessments of all types of GMOs, including those containing engineered gene drives.

[11] http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review

[12] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework