

**CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2018-103**

Submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology

Submission by Australia



**Australian Government**

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**NOTE: Information provided in this response has been primarily drawn from Australian Government agency input**

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**Notification 2018-103 - Submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology**

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Australia thanks the Secretariat for the invitation to submit information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology, as communicated in notification 2018-103 Ref.: SCBD/CP/DC/MA/MW/87791 of 14 December 2018.

Part one:

In decision 14/19, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) decided to extend the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology with renewed membership, taking into account, inter alia, and the work on risk assessment under the Cartagena Protocol, to work in accordance with the terms of reference annexed to the decision.

The COP also decided to extend the Open-ended Online Forum on Synthetic Biology, taking into account the work on risk assessment under the Cartagena Protocol, to support the deliberations of the AHTEG on Synthetic Biology, and invited Parties, other Governments, indigenous peoples and local communities and relevant organizations to continue to nominate experts to take part in the Online Forum on Synthetic Biology.

*Ad Hoc Technical Expert Group (AHTEG)*

Australia sought representation on the synthetic biology AHTEG, putting forward nine expert nominations for consideration however none of these nominations were accepted. We remain concerned if there is no Pacific representation on the synthetic biology AHTEG whilst undertaking the work outlined in decision 14/19.

We are therefore pleased to see decision 14/19 provides for a renewed membership of the AHTEG. When the call is made by the Executive Secretariat to nominate experts to participate, Australia will be pleased to again put forward expert nominations for consideration.

*Open-ended online forum (online forum)*

Australia supports the extension of an online forum to support the deliberations of the AHTEG. We consider the last open ended forum to have been a good mechanism to capture the different views of the large number of active participants.

We submit the following nominations of experts to be registered for the online forum:

- Dr Michael Dornbusch  
Assistant Secretary  
Evaluation Branch  
Office of the Gene Technology Regulator  
michael.dornbusch@health.gov.au  
+61-2-6289-1413

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- Dr Peter Thygesen  
Principal Regulatory Scientist  
Office of the Gene Technology Regulator  
peter.thygesen@health.gov.au  
+61-2-6289-1457
- Dr Heidi Mitchell  
Plant Evaluation Section  
Office of the Gene Technology Regulator  
heidi.mitchell@health.gov.au  
+61-2-6289-1477
- Dr Louisa Matthew  
Regulatory Practice Section  
Office of the Gene Technology Regulator  
louisa.matthew@health.gov.au  
+61-2-6289-1490
- Dr Owain Edwards  
Domain Leader, Environment & Biocontrol  
CSIRO Synthetic Biology Future Science Platform  
CSIRO  
Owain.Edwards@csiro.au
- Dr Claudia Vickers  
Director  
CSIRO Synthetic Biology Future Science Platform CSIRO  
Claudia.Vickers@csiro.au
- Dr Natalie Smith  
Chemicals and Biotechnology Assessments Section  
Department of the Environment and Energy  
Natalie.smith@environment.gov.au  
+61 6274 2637
- Dr Caitriona Dowd  
Chemicals and Biotechnology Assessments Section  
Department of the Environment and Energy  
Caitriona.dowd@environment.gov.au  
+61 6274 1963

Part two:

In decision 14/19, the COP invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide the Executive Secretary with relevant information to contribute to the work of the AHTEG, namely on:

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- (a) The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17;
- (b) New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group in December 2017, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process;
- (c) The current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account the traits and species potentially subject to release and the dynamics of their dissemination; and
- (d) Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.

We note that the outcomes of the agreed processes will be submitted for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) at its twenty-fourth meeting to be held in 2020.

Please see our input against a-d of the notification below.

***a) New and emerging criteria assessment of synthetic biology***

Australia would like the issue of whether or not synthetic biology is a new and emerging issue finalised as soon as possible so that already scarce resources are not inappropriately directed towards items which are not aligned with the Convention's strategic plan and work programme.

Australia remains concerned that work on synthetic biology is still being progressed, despite no agreement that it meets all seven criteria for a new and emerging issue. Agreement to an ongoing work programme, prior to assessment against the criteria, sets an unfavourable precedent that will undermine this agreed process for adding new issues to the Convention's agenda in a transparent way and with the agreement of all Parties.

An assessment by the AHTEG against the new and emerging criteria has now been agreed at and mandated by three successive COP meetings. This robust assessment must be completed by the AHTEG, against all seven agreed criteria, as a first order priority.

We support the call for renewed membership of the AHTEG to occur as soon as possible, to facilitate the assessment.

We also wish to note the assessment of synthetic biology undertaken by the Executive Secretariat, attached to papers provided for the July 2018 SBSTTA22 meeting, stated "the analysis is not intended to provide final evidence as to whether or not synthetic biology should be considered a

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new and emerging issue, and does not imply that the AHTEG reached any conclusions on this matter”.

In regard to synthetic biology and how it relates to the seven new and emerging issue criteria, Australia considers that synthetic biology has relevance to the conservation and sustainable use of biodiversity. However, there is no evidence that the risks associated with synthetic biology organisms and products would be significantly different to those associated with organisms that occur naturally, are the product of conventional breeding techniques, those that have more recently been generated by modern biotechnology (e.g. genetically-modified organisms, living modified organisms) or industrial chemical products. On this basis, Australia considers that there is not new evidence of unexpected and significant impacts on biodiversity, and therefore there is no urgency to address potential risks. In light of existing international and domestic regulatory frameworks to minimise the risks to biodiversity, there is no evidence of the absence or limited availability of tools to limit or mitigate negative impacts. Current risk identification and assessment methodology as outlined in the Cartagena Protocol and Australia's Risk Analysis Framework (Office of the Gene Technology Regulator, 2013) is equally applicable and adequate to assess risks from synthetic biology.

Australia has recently undertaken a review of its national regulatory scheme for gene technology. In regard to synthetic biology, the final report<sup>1</sup> recommends the following:

Recommendation 5:

- a. Extensions and advancements of gene technology, such as synthetic biology, continue to remain within the scope of the Scheme; and
- b. A watching brief on synthetic biology should be maintained, to ensure the appropriate level of regulation is applied to future applications of synthetic biology.

The review included consideration of any new technological developments in synthetic biology and concluded that all concrete applications of synthetic biology continue to remain within the scope of existing regulations, and a watching brief on synthetic biology applications be maintained.

***b) New technological developments in synthetic biology***

Australia continues to horizon scan for applications of technology that could be classified as synthetic biology. An example of relevant recent research is the discovery of phage-derived anti-CRISPRs, which have the potential to counteract CRISPR-mediated gene regulation and prevent genome editing<sup>2</sup>. Additionally, research has been published on genetic modification techniques that allow for the design of specialised organisms, creating an artificial biodiversity<sup>3</sup>.

Australia also continues to expand our development of synthetic biology applications. In February 2018, Australia's Gene Technology Regulator approved the commercial release of canola genetically modified for omega-3 oil content (DHA canola) to benefit agriculture and food production. The insertion of a multi-gene pathway to create a new oil profile in these plants is often described as

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<sup>1</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review#key-documents>

<sup>2</sup> <https://www.nature.com/articles/s41467-018-08158-x>

<sup>3</sup> <https://www.mdpi.com/2073-4425/10/1/17>

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synthetic biology. Australian scientists are also part of the international Synthetic Yeast 2.0<sup>4</sup> consortium who are engineering the genome of bread yeast. CSIRO's Synthetic Biology Future Science Platform continues to develop Australia's capacity for synthetic biology.

Australia is also continuing to build our knowledge and understanding of what synthetic biology actually is. In particular, Australia does not consider that all applications of genome editing necessarily result in synthetic biology organisms. Indeed many of the tools used in synthetic biology, including genome editing, can also be used for other non-synthetic biology applications. For example:

- Site-directed nucleases can be used to make a DNA cut allowing changes to be introduced at the disrupted site. These changes can range from small modifications indistinguishable from natural mutations to, in theory, entirely re-engineered genomes.
- DNA/RNA synthesis can be used to insert small changes in the genome of a virus or other organism. These changes may be unique or may reflect the genetic variability found within other strains of the same organism.

Australia's Commonwealth Science Council and Chief Scientist commissioned a report from the Australian Council of Learned Academies entitled "Synthetic Biology in Australia: An outlook to 2030", which was released in September 2018<sup>5</sup>. As a horizon-scanning report, it examines the opportunities and issues that synthetic biology will be likely to exert in Australia in the coming decade. Technological advancements are considered in four broad areas of synthetic biology applications: industry and energy, agriculture and food, environment and biocontrol, and health.

While the technical development of CRISPR gene drives is still under development, parallel research is showing that the self-replication mechanism (termed homing) which allows CRISPR gene drives to spread through a population is inefficient and unlikely to spread widely in time or space due to "resistant" alleles generated when homing fails to occur. As such, alternative genetic strategies for population suppression or replacement have recently started to be considered. One of these is the targeted deletion of an entire sex chromosome which has the potential to bias population sex ratios. Unlike standard CRISPR gene drives, homing is not required in such approaches for spread of the transgene and replication resistant alleles will not be generated. The population suppression of undesirable invasive species has now moved beyond a classic gene-drive approach<sup>6</sup>.

***c) The current state of knowledge on the potential positive and negative environmental impacts of current and near-future applications of synthetic biology***

Australia notes and reiterates that, in relation to potential positive and negative environmental impacts of applications of synthetic biology, it is important to distinguish between synthetic biology techniques undertaken in controlled, contained facilities and the environmental release of

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<sup>4</sup> <http://syntheticyeast.org/sc2-0/>

<sup>5</sup> <https://acola.org.au/wp/sbio/>

<sup>6</sup> Adikusuma F, Williams N, Grutzner F, Hughes J, Thomas P. (2017a) Targeted Deletion of an Entire Chromosome Using CRISPR/Cas9. *Molecular Therapy* 25, 1736-1738. Fatwa Adikusuma, Sandra Piltz, Mark A. Corbett, Michelle Turvey, Shaun McColl, Karla Helbig, Michael Beard, James Hughes, Richard T. Pomerantz & Paul Thomas (2018) Large deletions induced by Cas9 cleavage. *Nature* 560 (7717), E8

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organisms derived from synthetic biology. Australia also acknowledges the large field of information available internationally on the requirements for the safe containment of organisms in research and manufacturing.

With some exceptions, for example, DHA canola as cited above, most applications of synthetic biology in the near future are likely to be confined to laboratory research or contained manufacturing. It is difficult to predict how soon synthetic biology organisms may be ready for consideration of wider environmental release. However, it is unlikely that commercial applications of synthetic biology (especially organisms) proposed in the near future would not be categorised and regulated as gene technology and genetically modified organisms in Australian and other national legislation, or as modern biotechnology and living modified organisms in the Cartagena Protocol on Biosafety.

No negative impacts on human health and safety or the environment were identified during field trials of the DHA canola mentioned above and the Gene Technology Regulator's assessment was that a commercial release would pose negligible risks and did not require any specific risk treatment measures<sup>7</sup>. Likewise, Australia and New Zealand's food regulator (Food Standards Australia New Zealand) assessed that foods derived from DHA canola are as safe to eat as food derived from conventional canola<sup>8</sup>.

Specifically in relation to gene drives, there are no proposals for release in Australia.

***d) Living organisms developed that may fall outside the definition of living modified organisms as per the Cartagena Protocol***

Australia is currently not aware of any living organisms developed through synthetic biology that would not be considered genetically modified organisms under the Australian gene technology regulatory scheme. It is our assessment that organisms currently being produced within the synthetic biology field would be covered by definitions in the Cartagena Protocol on Biosafety as well as those in Australia's gene technology legislation.

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<sup>7</sup> <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR155>

<sup>8</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1143-DHA-Canola-Line-NS%E2%80%9393B500274.aspx>