CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2017-025

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

Submission by Australia

NOTE: **All information provided in this response has been drawn from Australian Government agency input only.**

Notification 2017-025 Submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology

Australia is responding to the invitation to Parties to the Convention on Biological Diversity, other Governments, relevant organisations and indigenous peoples and local communities to:

(b) submit information and supporting documentation relevant to the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology as referenced in paragraph 10 of decision XIII/17, and

(c) nominate experts to participate in the Open-ended Online Forum on Synthetic Biology.

Australia thanks the Secretariat for the opportunity to provide input on these matters.

Please note Australia will make nominations for the ad hoc technical expert group on synthetic biology through a separate submission before the 30 June 2017 due date.

Introductory remarks

Australia reiterates key points from its previous submission on synthetic biology (2015-013). In particular, it is Australia's view that:

- current synthetic biology applications are not qualitatively different from modern biotechnology
- synthetic biology, and any organism that is produced by this means, would be covered by definitions in the Cartagena Protocol on Biosafety, as well as, Australia's gene technology legislation
- current risk identification and assessment methodology as outlined in the Cartagena Protocol and Australia's Risk Analysis Framework 2013 is equally applicable and adequate to assess risks from synthetic biology
- it is important to distinguish between synthetic biology techniques undertaken in containment and environmental release of organisms derived from synthetic biology
- Australia supports a case by case, science-based risk-assessment of synthetic biology applications to identify plausible risks to biodiversity and related human health. Management of identified risks (if any) should be consistent with relevant international obligations and current regulatory frameworks for Living Modified Organisms (LMOs)
- synthetic biology does not meet the criteria of a new and emerging issue, but Australia is willing to engage in discussions anchored in sound science to explore whether there are synthetic biology applications capable of posing inherently different risks to biological diversity that fall outside of the Cartagena Protocol.

(a) submit information and supporting documentation relevant to the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology as referenced in paragraph 10 of decision XIII/17.

In response to those elements detailed in paragraph 10 of decision XIII/17, Australia wishes to submit the following information:

(a) Research, cooperation and activities noted in paragraph 9 of decision XIII/17

For two decades, Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO), the principal agency for scientific research in Australia, has conducted benchmark research on the development of genetic based biological control technologies for invasive species management, both plant and animal.

These include:

i) insertion of gene constructs to manipulate sex expression in invasive species in the context of meiotic gene-drives based on Mendelian inheritance (so called "daughterless" or "sonless" approaches);

ii) immuno-contraception, which involves the use of an animal's immune system to prevent it from fertilizing offspring for the control of vertebrate pests like mice and foxes, through the genetic manipulation of specific viruses as delivery mechanisms;

iii) the use of RNA interference creation and delivery to regulate gene expression to reduce fitness of pest organisms; and

iv) initial studies of the potential of CRISPR gene-drive approaches.

As the authority responsible for the regulation of work with LMOs in Australia since 2001, the Gene Technology Regulator (the Regulator) has applied Australia's Risk Analysis Framework to produce scientific risk assessments for the conduct of the above research, and all work with LMOs in Australia. The Regulator uses these risk assessments and associated risk manangement plans to guide decisions on whether or not to authorise work with LMOs and to identify relevant conditions which should be imposed. This has enabled the safe research and work with LMOs in Australia.

CSIRO has many peer reviewed publications that can be supplied to support the pre-deployment research, scientific risk analysis, management strategies and post-deployment analysis of the use of these approaches. Synthetic biology provides new opportunities to develop biological control systems. CSIRO is building on its 100 year history in the development of classical biological control solutions for managing invasive species causing environmental harm to understand the best approaches and scientific risks of synthetic biology based biological control.

In addition CSIRO has a new research initiative which has established a series of Future Science Platforms (FSP) including one for Synthetic Biology. The Synthetic Biology FSP acts as a collaboration hub supporting synthetic biology research both within CSIRO and across Australia through university research partners. Activities include projects focussed on developing synthetic biology based solutions to protect the environment and biodiversity; and projects feeding into risk assessment, including modelling ecological responses to interventions. The Synthetic Biology FSP is also developing a research program in understanding social, ethical, regulatory, and legal issues related to synthetic biology.

The Australian Council of Learned Academies (ACOLA) is currently developing a report entitled "The future of Synthetic Biology in Australia". The report has been commissioned through the Office of the Chief Scientist and will be delivered by June 2018 for consideration by the Prime Minister's Commonwealth Science Council.

(b) *Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention*

Although there is no hard data evidence from work conducted by CSIRO to support the above aims, experience gained from work conducted by the University of Queensland and Monash University introducing new strains of the bacterium *Wolbachia* into *Aedes* mosquitoes in an effort to reduce their potential to be efficient vectors for *Dengue Fever Virus* may provide insights.

(c) *Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks*

CSIRO has developed a risk analysis platform for understanding the scientific risks of releasing living modified organisms and funded projects to conduct risk assessments of both gene drive containing LMOs (in the first instance, the mouse) and the use of externally applied biological agents (namely small RNA to effect transient RNA interference effects). CSIRO is involved in international discussions and collaborations to advise and inform the risk assessment frameworks to better fit the issues of concern in the release of gene drive containing LMOs.

The Regulator has not received any applications for work with organisms badged as synthetic biology organisms. However, the Regulator has produced risk assessments for genetically modified viruses containing substantial percentages of genetic material from multiple organisms, whereby comparison to a single parental organism is not practical. Australia was able to adapt current risk assessment procedures to perform an assessment based on the total risk posed by the LMO rather than assessing potential risks arising from differences between the LMO and its parent organism. It is expected that this approach will be able to be applied to risk assessments for synthetic organisms for which there is no relevant parent organism.

(d) *Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology*

Australia's Regulator has a rigorous scheme in place for the regulation of all living modified organisms, including synthetic biology organisms. This includes requirements for containment and safe handling of LMOs not authorised for release, and provisions to impose licence conditions if LMOs are being released into the environment[1]. Recently the Regulator also issued Guidance on the Regulatory requirements for contained research with GMOs containing engineered gene drives[2]. This includes information on the current regulation of organisms containing gene drives as well as advice on appropriate containment levels and measures. It is also important to note that the OGTR has developed different physical certification requirements tailored to different types of organisms. For example, the containment features and work practices required for a Plant Facility will be different to those for a Invertbrate Facility (e.g .for work with insects) or a Animal Facility (e.g. for work with mice), with the differences taking account of the different biology of the subject organisms[3]. The OGTR has guidelines for a range of

[1] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/section-working-with-gmos

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

[3] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/FacilTypesv1-2-htm

different facility types and these are available from the OGTR website[4]. It should also be noted that Institutional Biosafety Committees play an important role in the Australian regulation of contained GMO research, both in the correct classification of approvals required and in 'on the ground' oversight of adherence to containment and other risk management requirements. It should be further noted that OGTR undertakes monitoring of lab-based research for compliance with regulatory requirements with a focus on higher risk activities, eg higher level containment faciltiies.

Laboratory-based research relating to synthetic biology within CSIRO is conducted at Physical Containment level 2 (PC2) as a minimum. Minimum containment requirements for work with GMOs are set by the Gene Technology Regulations 2001 or through specific licence conditions imposed by the GT Regulator.

Through dialogue between research organisations and regulators regarding the conduct of synthetic biology, research in the field of gene-drives is to be conducted using the conditions set by the GT Regulator and, if needed, supplemented by controls suggested in peer review articles. In particular, the genetic control by the use of "split gene-drive" components, artificial genomic targets and laboratory strains of animal rather than wild strains. When a unified gene-drive is being considered in a non-laboratory strain of animal, CSIRO has proposed that this would be conducted at PC3 level containment. CSIRO is the managing body for the Australian Animal Health Laboratory, with animal facilities that operate at this highest level of physical containment. Work of this nature is not yet underway nor are funds yet assigned for such work.

(e) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology

As referenced above, the Regulator has legislation, regulations and guidelines in place that regulate all LMOs including synthetic biology. Please see the Australian Government submission to notification 2016-041 for further information on Australia's scheme and requirements - http://bch.cbd.int/database/record.shtml?documentid=110410

CSIRO is funded by the Australian Government and has a role as trusted advisor in areas of particular scientific expertise. CSIRO and other organisations work closely with national regulators to provide impartial advice relating to the potential benefits or risks of synthetic biology-based technologies and for the development of guidelines, policies and regulations pertaining to developments in synthetic biology and their impacts on environment and health. CSIRO only provides advice in this area and has no formal responsibility.

(f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology

Through the recently establish Synthetic Biology Future Science Platform and its re-instigated Gene Technology Working Group, CSIRO will continue to build capability in the areas of scientific risk analysis. In addition to this, CSIRO has specific liaison with indigenous people's groups and will continue to work closely with them where synthetic biology activities have applications or implications for the natural environment.

[4] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc2-1
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc3-1
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/cert-pc4-1

(b) nominate experts to participate in the Open-ended Online Forum on Synthetic Biology.

Australia would like to **nominate** the following nine experts to be considered as forum members:

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Australia also kindly requests **removal** of the following people from the forum:

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