CONVENTION ON BIOLOGICAL DIVERSITY (CBD) NOTIFICATION 2015-139

Peer-review of Reports on Synthetic Biology
Submission by Australia

CBD Notification 2015-139: Peer-review of Reports on Synthetic Biology

Australia is responding to the invitation for Parties, other Governments, relevant organisations and Indigenous peoples and local communities to the Convention on Biological Diversity (the Convention) to peer-review the following documents:

i. *Updated report and synthesis of views in response to paragraph 7(b) of Decision XII/24* (Synthesis Report)*; and*

ii. *Report of the meeting of the Ad Hoc technical expert group on synthetic biology* (AHTEG Report).

Considering the content of the two reports, the Australian Government would like to reiterate the comments made in the submission in response to notification 2015-013.

This submission addresses the key messages of both the Synthesis Report and the AHTEG Report, which reflect the progression of discussions over the last twelve months.

Please note that all item and paragraph references in the points below relate to paragraphs of the AHTEG Report

Key Points

1. Decision XII/24 indicates the Ad hoc Technical Expert Group (AHTEG) has an important role in gathering and synthesising information on synthetic biology, which would contribute to a robust reassessment of synthetic biology against the criteria for a 'new and emerging issue' under the Convention. It is therefore unclear why the AHTEG has not proposed a reassessment of synthetic biology as part of the next steps detailed in Item 4 of the AHTEG Report. This matter should be resolved before substantial further work on synthetic biology is considered.
2. The AHTEG's discussions have not completely focused on synthetic biology as it relates to the three objectives of the Convention. Broadening the discussions beyond a scientific perspective (i.e socio-economic, moral and ethical considerations) adds significantly complex concepts to discussions and may detract from seeking a science-based assessment of how synthetic biology has the potential to impact or benefit biological diversity.

Reassessment of synthetic biology as a new and emerging issue

At its twelfth meeting, the Conference of the Parties (COP) to the Convention concluded that there was *"insufficient information available to finalise an analysis, using the criteria set out in Paragraph 12 of Decision IX/29, to decide whether or not this is a new and emerging issue related to the conservation and sustainable use of biodiversity"*[1]. Further to this, the COP *"Awaits the completion of a robust analysis using the criteria set out in paragraph 12 of Decision IX/29"*[2].

The synthetic biology AHTEG Report makes a number of recommendations to the Subsidiary Body for consideration at its twentieth meeting. Currently, the AHTEG Report does not include a recommendation to consider a reassessment.

Further information appears to have become available through the online forum, submissions and discussions of the AHTEG. Consideration should be given to fulfilling paragraphs 1 and 2 of Decision XII/24, via complete and robust analysis of synthetic biology against the criteria set out in Paragraph 12 of Decision IX/29.

[1] Decision XII/24, paragraph 1.
[2] Decision XII/24, paragraph 2.

Item 3 – Substantive Issues

3.1 Operational definition

Australia notes the operational definition proposed by the expert group:
"Synthetic biology is a further development of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems".

3. Noting the terms of reference for the AHTEG (Annex to Decision XII/24), the AHTEG has not developed any inclusion and exclusion criteria to support this definition (i.e. to help determine similarities and qualitative and substantial differences from 'modern biotechnology').
4. This definition is focused on an aspect of discussion where there is general consensus between Parties; that synthetic biology is an extension of modern biotechnology. However, the proposed definition cannot be used to determine whether a component, product or organism is considered to be an application of synthetic biology or not.
5. Paragraph 22 of the AHTEG Report states that the AHTEG supported a definition that "*would express the notions of both continuity and novelty...*". Currently, the definition does not address the role of novelty in defining synthetic biology.
6. Because synthetic biology forms part of a continuum of biotechnology applications, agreement to an operational definition (with inclusion and exclusion criteria) may continue to be elusive. Care must be taken to ensure the effort and time taken to develop the definition does not exceed the value of such a definition. Time may be better spent in identifying/cataloguing applications referred to as synthetic biology that do not fall within existing definitions and determining whether they may realistically pose unique and significant threats to biological diversity, which require addressing under the Convention.

3.2 Relationship between synthetic biology and biological diversity

7. The AHTEG Report does not present a consolidated summary of the key relationships (interactions) between synthetic biology components, products and organisms and biological diversity. However, the key pathways identified in the AHTEG Report appear to be: feedstocks and wastes, chemical pathways, genetic pathways and ecological disruption. The AHTEG Report does not provide compelling information to suggest that these interactions are new or inherently different to those resulting from existing, conventional industrial or biotechnological activities.
8. Paragraph 27 states: *"...in order to facilitate discussions on the relationship between synthetic biology and biological diversity, an appropriate baseline for measuring the potential positive and negative impacts of synthetic biology on each of the objectives of the Convention needs to be considered or developed..."*. This point needs to be clarified in the revised AHTEG Report and further information provided as to why synthetic biology should be differentiated from other sources of potential harm for which there is no clear 'baseline'. We also suggest that a baseline (if needed) is likely to be different for each application and should be determined on a case-by-case basis (and could include comparison with any existing conventional methods or processes used to produce the same outcome).
9. Paragraph 30 notes the importance of considering "*potential positive and negative indirect effects*" when considering the relationship between synthetic biology and the objectives of the Convention. It is essential that only those indirect effects that *are probable* and can be *reasonably attributed* to synthetic biology applications are considered.

3.3 Similarities with LMOs

10. Australia notes the common understanding of 'components' as non-living parts of a process, 'products' as the non-living outputs of a process and 'organisms' as the living parts and outputs of a process.
11. Paragraph 35 states that "*...it is not clear at the current stage whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the definition of LMOs...*". It would be useful if the AHTEG Report provided some examples. We would expect any synthetic organism to have some 'novel combination of genetic material'.

3.4 Adequacy of existing regulatory instruments

12. Without sufficient detail or justification, paragraph 38 states that "*...living organisms, components and products of synthetic biology fall within the scope of the Convention and its three objectives*". A robust reassessment of synthetic biology against the criteria for a 'new and emerging issue' is required for this claim to be made with confidence.
13. Paragraph 38 goes on to state that "*...many components and products of synthetic biology, while covered by the Convention, are not covered under the scope of the two Protocols and possibly not by some national biosafety frameworks either*". Components and products of synthetic biology generally fall under the scope of other instruments and regulatory frameworks that cover therapeutic goods, agricultural chemicals or industrial chemicals. It remains appropriate at the international, regional and national level for the regulation of products that are chemically-defined entities to focus on their intended use and their relevant physical and chemical properties, not on the process by which they were created.
14. Paragraph 41 refers to needs with regard to international regimes, which include:
    a. "*provisions to address the socioeconomic impacts of the components and products of synthetic biology*". Australia reiterates support for a case-by-case, science-based risk assessment. Any guidance on socio-economic considerations must be voluntary, considered as part of existing national regulatory frameworks and take into account and be consistent with other international obligations.
    b. "*measures to minimise the likelihood of unintentional transboundary movements of organisms of synthetic biology after their release into the environment*". This is inconsistent with previous statements that current and near-future synthetic biology organisms are similar (or identical) to LMOs, which suggests that synthetic biology organisms are covered by the Cartagena Protocol. The Cartagena Protocol has appropriate provisions to manage unintentional transboundary movements (Article 17 of the Protocol).
15. Although no formal gap analysis has been carried out, it would be useful for the AHTEG to provide an initial position or overview on the level of coverage or the adequacy of existing instruments to regulate the components, products and organisms of synthetic biology (as per Paragraph C of the AHTEG's Terms of Reference).

3.5 Potential benefits and adverse effects

16. Section 3.5 of the AHTEG Report considers the potential benefits and adverse effects of components, products and organisms of synthetic biology. The list of benefits and adverse effects also apply to conventionally-derived products, conventionally-bred plant species and LMOs. Therefore, the risks associated with synthetic biology components, products and organisms are not inherently different.

17. Paragraph 44 states "*However, the potential positive and negative impacts of synthetic biology may be broader and more wide-ranging, due to the potential of synthetic biology to engineer more complex organisms and biological systems for use in a varied range of applications*". It is unclear how the AHTEG came to this conclusion, when synthetic biology generally seeks to minimise the number of genes in order to focus on a particular function, which is intended to lead to more predictability in the resultant organism.
18. Paragraph 47 draws a link between synthetic biology and ethical views towards nature. The AHTEG must ensure that discussions remain tightly focused on the objectives of the Convention and remain science-based. Ethical considerations are informed by national and cultural values; consequently, this would significantly add to the complexity of discussions.
19. Paragraph 49 – it is unclear what the AHTEG is communicating in this point. However, it does illustrate the difficulty in isolating synthetic biology as a unique and stand-alone issue.
20. Paragraph 50 – relates to socioeconomic impacts. Australia reiterates support for a case-by-case, science-based risk assessment. Any guidance on socio-economic considerations must be voluntary, considered as part of existing national regulatory frameworks and take into account and be consistent with other international obligations.
21. Paragraph 51 states that "(Synthetic biology applications) *are at various stages of development, ranging from the theoretical to early or active areas of research to those that are already on the market*". The AHTEG should provide examples of synthetic biology components, products and organisms that are currently available on the market. As the proposed operational definition does not have inclusion and exclusion criteria, how can it be confidently stated that these items are not instead the result of modern biotechnology applications?
22. The following general comments relate to the list of potential benefits and adverse effects of synthetic biology:
    a. extensive modification, combined with the removal of 'non-essential' genes is likely to lead to an organism with vastly reduced fitness and capacity to survive and persist in the environment[3];
        - For example, the application of xenobiology would result in organisms that can't pass their genes on to other organisms and may not be able to survive in the wild, where the required artificial nucleotides/amino acids are not available. This is likely to improve the ability to contain these organisms and their genetic material and prevent harm from unintentional release.
    b. all potential adverse effects that are listed by the AHTEG have also been identified as potential adverse effects of LMOs. Established procedures are in place to assess and manage these risks;
    c. increased pathogenic potential would be a benefit, if it is pathogenic towards a pest or invasive species;
    d. Intentionally-designed toxicity would be a benefit if it is targeted to specific pest or invasive species and resulted in reduced non-target effects compared to conventional pesticides or herbicides.

3.6 Best practices on risk assessment and monitoring

23. We would like to add Australia's Gene Technology Regulator's *Risk Analysis Framework* 2013[4] as a further example of best practice risk assessment.

[3] http://www.nature.com/nchembio/journal/vaop/ncurrent/full/nchembio.2002.html
[4] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework

24. Information on Australia's current approach to monitoring for compliance with the requirements of our gene technology legislation can be found in a variety of relevant documents, available on the website of the Gene Technology Regulator[5].
25. Australia questions the inclusion of The ETC Group's "*The Principles for the Oversight of Synthetic Biology*" document as an example of best practice risk assessment and monitoring. The moratorium on environmental release proposed in this document is inconsistent with Paragraph 3 of Decision XII/24, which allows for environmental release following a full risk assessment in accordance with national, regional and/or international frameworks.

3.7 Degree to which the existing arrangements and mechanisms are comprehensive

26. Paragraph 58 – Expansion of existing frameworks for regulating LMOs at the international, regional and national level is considered to be the best approach for managing potential risks of synthetic biology. This allows more streamlined processes and for a scientific, stepwise approach to be taken, building on the experience and knowledge accumulated in relevant institutions related to LMO risk assessment and control. For example, the Australian legislation regulating gene technology and genetically-modified organisms (equivalent to LMOs) is subject to periodic review, to respond to technology developments, such as those described as synthetic biology and to ensure that regulation is commensurate with risks.
27. Paragraph 61 refers to socioeconomic considerations related to the impacts of synthetic biology not being sufficiently addressed by existing frameworks.
    a. Australia reiterates its view that socioeconomic considerations in the regulatory process for LMOs and synthetic biology has the potential to detract from science-based risk assessment and management. Socioeconomic concerns also have the potential to add more complexity to discussions.
    b. Any amendment of frameworks to incorporate socioeconomic considerations must be voluntary and applied in a manner consistent with national legislation and other international obligations. Any inclusion of such considerations must also be transparent, consistent and clearly distinguished from science-based aspects of the risk assessment.
28. The AHTEG should provide examples of how ethical values may be appropriately integrated into science-based risk assessment methodologies related to the objectives of the Convention. The AHTEG should also consider the extent to which ethical guidance is already available in other international fora.

Item 4 – Conclusions and ways forward, including elements to facilitate future discussions and actions on synthetic biology under the Convention

29. The proposed recommendations for a way forward on synthetic biology under the Convention should rest upon a reassessment against the criteria of a 'new and emerging issue' (Decision IX/29), as per Paragraphs 1 and 2 of Decision XII/24. The proposed work programme under this item seemingly pre-empts, in part, the outcome of a reassessment.
30. The proposed recommendations would also involve the allocation of substantial resources from the Convention's Secretariat to undertake these activities, which may detract from other priorities such as enhancing implementation and progress towards the Aichi Targets. In addition, more analysis of information relating to synthetic biology and knowledge gaps currently being considered under other international fora is needed before the proposed work programme can proceed. This is important to avoid duplication across other international agreements considering this issue and to enhance synergies.

[5] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/section-regulatory-compliance