Submission to the Senate Inquiry on Environmental Biosecurity

Synthetic biology – a new and emerging field
The field is evolving so rapidly that even scientists working in it haven't yet agreed on a definition[1], but in essence synthetic biology (synbio) is an extreme version of genetic engineering. Instead of swapping genes from one species to another (as in genetic engineering), synthetic biology creates entirely new forms of life - or reprograms organisms to do things that would not naturally occur. Synbio uses a variety of techniques, including constructing synthetic (human made) DNA.

Synthetic biology is about to enter the market via new ingredients for food, cosmetics and household products. These new ingredients, including synbio versions of vanilla, stevia and saffron flavorings for food and beverages, and ingredients for cosmetics and cleaning products, are produced by synthetically engineered organisms, including synbio yeast and algae that are raised in vats and fed on sugar.

Synthetic biology poses grave new biosecurity risks
Synthetic biology creates highly novel, living artificial organisms – termed synthetically modified organisms (SMOs). These have the potential to persist and reproduce in nature. There exists no guidance on how to assess and manage SMOs for biosecurity risks.

Synthetic biology companies produce billions of novel SMO strains, raising serious questions about monitoring, recall and liability. For example, Harvard's Wyss Institute has developed a technology called multiplex automated genome engineering (MAGE). They used the technology to simultaneously modify 24 genetic components of the gut bacteria *Escherichia coli,* producing over 4.3 billion genetic variants per day. These were then screened for desirable traits.[2]

A recent draft report by the Convention Biological Diversity's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) raises the concern that:

> *"If synthetic biology succeeds in producing sufficiently hardy micro-organisms, they could present new biosafety concerns through their potential to transfer synthetic DNA, adapt and evolve to new environments, and impact other organisms in the ecosystem. The ability to address these concerns is constrained by our comparatively limited understanding of these processes in micro-organisms as opposed to multicellular organisms."*[3]

While the majority of proposed synbio applications are for contained lab use, the potential consequences of the accidental release of SMOs into the environment could pose a serious biosecurity threat. As the SBSTTA observes:

> *"There is debate over the degree and probability of harm that organisms resulting from synthetic biology techniques intended for contained use could cause if released. There is a low probability that synthetic biology organisms which were engineered for contained use and which are released accidentally could survive and propagate. On the other hand, the majority of research in synthetic biology uses microbes as hosts which have a particularly high potential for mutations. Once released into the environment these organisms cannot be retrieved and could potentially represent a*

catastrophic risk. Such a low-probability and high- consequence situation raises ethical issues around harms, benefits and risks."[4]

Some ecologists note that, since micro-organisms have a high potential for evolutionary change, even ones that are unlikely to survive outside of contained use may evolve to become more successful in the environment, raising potential biosecurity concerns.[5]

There are biosecurity concerns associated with the accidental or intentional release of SMOs used for bioenergy purposes. For example, the use of synbio microalgae for bioenergy purposes may have adverse ecological impacts, particularly if grown in open ponds and thus with a higher chance of accidental release.[6]

A number of proposed synbio applications would involve deliberate environmental release, potentially posing serious potential biosecurity impacts.

Bioweapons and health concerns
Synthetic biology allows for the construction of viruses and bacteria that could be infectious or otherwise harmful to humans and/or animals – either purposefully or by mistake. As the Convention on Biological Diversity observes:

> *"Components, organisms and products resulting from synthetic biology may be intentionally or unintentionally released to the environment, leading to biosafety concerns. Depending on the circumstances, they could be considered to pose risks to animal or plant life or health, through ecosystem-level impacts or the transfer of synthetic DNA."*[7]

The National Centre for Biosecurity, a collaborative undertaking by The Australian National University and The University of Sydney, has looked at these issues in some detail.[8]

Biohacking
There is a growing community of 'biohackers' – encouraged by such initiatives as the International Genetically Engineered Machine (IGEM) competition - conducting exploratory synbio research in labs and garages around the world – raising serious potential biosecurity concerns and serious challenges for regulators.

In theory, using a laptop computer, published gene sequence information and mail-order synthetic DNA, just about anyone has the potential to construct genes or entire genomes from scratch (including those of lethal pathogens). Biohackers are often computer hackers with little or no understanding of the potential dangers associated with biohacking, and no systems in place to avoid the accidental release of synthetic organisms.

Current regulatory regimes are inadequate
Regulatory regimes for SMOs have yet to be developed anywhere in the world. Existing regulations to govern genetic engineering were developed before the emergence of synthetic biology techniques. These are inadequate to provide safe and just oversight.

As the SBSTTA observes:

> *"The international regulatory framework is not well equipped to address the potentially "catastrophic" and "existential" risks, with low and very low probability,*

but immense impacts, that are discussed in the context of some synthetic biology techniques."[9]

These novel organisms pose serious challenges for existing regulatory regimes. As the SBSTTA points out:

> *"Synthetic biology techniques can be used to insert hundreds or thousands of traits from different donor organisms, which then interact with each other challenging assessments based on assessing the risks of comparable counterparts of donor and parent organisms... Some researchers reflect a concern for the "unknown unknowns" of synthetic biology in their call for significantly increased funding for dedicated synthetic biology risk research. They argue that no one yet understands the risks that synthetic organisms pose to the environment, what kinds of information are needed to support rigorous assessments, or who should collect such data."*[10]

In Australia – as in other jurisdictions - the risk assessment of genetically modified organisms (GMOs) is based on the concept of 'substantial equivalence'. This involves comparing the genetically modified organism to its parent organism. Our Australian GMO regulator - the Office of the Gene Technology Regulator (OGTR) has conceded that "products of synthetic biology, lack an easily definable parent species" rendering this already highly controversial approach even less appropriate.[11]

Recommendations
Friends of the Earth is calling for a moratorium on the environmental and commercial release of Synthetically Modified Organisms (SMOs) until a binding international legal framework can be developed to regulate the risks posed by synbio.

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[1] OECD (2014) Emerging Policy Issues in Synthetic Biology, http://www.oecd-ilibrary.org/science-and-technology/emerging-policy-issues-in-synthetic-biology_9789264208421-en

[2] SBSTTA (2014a) NEW AND EMERGING ISSUES RELATING TO THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY - POTENTIAL POSITIVE AND NEGATIVE IMPACTS OF COMPONENTS, ORGANISMS AND PRODUCTS RESULTING FROM SYNTHETIC BIOLOGY TECHNIQUES ON THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY, p. 10.

[3] SBSTTA (2014a), p. 5.

[4] SBSTTA (2014a), p. 5.

[5] SBSTTA (2014a), p. 4.

[6] Snow, A.A. & Smith, V.H. (2012) Genetically Engineered Algae for Biofuels: A Key Role for Ecologists. *BioScience* **62(8)**: 765-768.

[7] CBD (2014) SYNTHETIC BIOLOGY: UPDATED REPORTS, www.cbd.int/doc/meetings/cop/cop-12/official/cop-12-20-en.doc

[8] See for example: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/ibcforum2011-3/$FILE/DualUse_IR.pdf

[9] SBSTTA (2014b) NEW AND EMERGING ISSUES RELATING TO THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY - POSSIBLE GAPS AND OVERLAPS WITH THE APPLICABLE PROVISIONS OF THE CONVENTION, ITS PROTOCOLS AND OTHER RELEVANT AGREEMENTS RELATED TO COMPONENTS, ORGANISMS AND PRODUCTS RESULTING FROM SYNTHETIC BIOLOGY TECHNIQUES

[10] SBSTTA (2014a), p. 5.

[11] OGTR (2013) Risk Analysis Framework, p.30, http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/42D3AAD51452D5ECCA2574550015E69F/$File/raffinal5_2.pdf