

Submission to the Australian Department of the Environment for the SBSTTA meeting on synthetic biology, LMOs and invasive species

Thanks for this opportunity to comment on the Department of the Environment's draft positions on synthetic biology (synbio), LMOs {Genetically Manipulated Organisms (GMOs)} and invasive species, for the forthcoming SBSTTA meeting.

We ask the Department to create more ongoing opportunities for the interested public to participate in CBD and related processes. We also ask the Department to be more responsive to public views and the public interest instead of evidently aligning its views with CropLife and its members.

The Department of the Environment's role is to be an honest broker in these international discussions and advance the public interest. But CropLife appears to have the Department's ear. CropLife is a network operating in 91 countries that represents the handful of major seed and agrichemical companies that now own and control most commercial seed worldwide, including all GM seed, and a majority of agrochemicals.

The Department appears to have advocated for none of the matters which civil society groups proposed for previous SBSTTA and CBD meetings. Public discussions can only be democratic and fair if they inform Government negotiations and full feedback is provided.

Our reflections on synbio, GMOs (LMOs) and biocontrol of invasive species follow.

Recommendations

- The Australian government should prioritise signing and ratifying the Cartagena Protocol to fully participate in the Protocol's work, the Biosafety Clearing House, and the CBD, as an essential feature of Australia's Biosecurity protection measures;
- Australia to advocate for an international process or mechanism to monitor synbio innovations and deployments, with the Biosafety Clearing House possibly appropriate;
- The Australian Department of the Environment to advocate in government and publicly for a moratorium on all field trials or general release of organisms containing gene drives;
- The Australian Department of Environment to adopt a program of work on synthetic biology, similar to that laid out in the IUCN's document IUCN WCC-2016-Res-086-EN¹;
- The Department of Environment to take a brief to SBSTTA, the CBD and the Cartagena Protocol that reflects the public interest instead of the interests of CropLife and its member companies.

Synthetic biology techniques - new and emerging

Synthetic biology (synbio) – many new GM techniques - synthesizes DNA to create novel organisms that have either never existed in nature, or that evolution tried but discarded.

The CBD must treat synbio as new GM techniques, raising many new and emerging issues. The Australian Government must not align itself with the GM industry, which argues that synbio is

¹ Development of IUCN policy on biodiversity conservation and synthetic biology, IUCN WCC-2016-Res-086-EN. https://portals.iucn.org/library/sites/library/files/resrecfiles/WCC_2016_RES_086_EN.pdf

not new or emerging and therefore not a topic for discussion at SBSTTA, CBD or anywhere else that may influence their corporate interests.

Synthetic biology transcends the now defunct cut-and-paste 'transgenic' GMOs, proponents claim. Synbio Research and Development (R&D) are rapidly expanding as new genome manipulation processes and cheaper DNA synthesis make it easier and faster to manipulate bio-systems and genetic materials. Slow down.

Synbio products entering markets from labs already include food flavourings and ingredients, fragrances and cosmetics, biofuels, drugs, textiles, and industrial chemicals. Commercial synbio crops, insects and animals may also be near.

CSIRO and the University of Adelaide are engaged in US military-funded (DARPA) gene drive (extinction) research, intending to release rodents on some off-shore islands for population wipeout.² The Wardang Island fiasco with calicivirus should warn us to reign in our hubris.

The precautionary principle and synbio

The Australian Government and GM corporations should not be aligned. Their PR front entity CropLife wants to restrict the scope of precaution to the environment alone but it is not the only public asset at risk. We back the Convention of the Parties (COP) and Ad Hoc Technical Expert Group (AHTEG) in support of precaution on environment impacts, as well as the ethical, economic social and cultural impacts of synbio.

The Convention on Biological Diversity (CBD) has 3 main objectives:

- conserving biodiversity;
- sustainably using components of biodiversity; and
- fairly and equitably sharing the benefits from using genetic resources.

Synbio threatens all three CBD goals if Parties fail to deliver:

- Operational Definition of synthetic biology;
- Gene Drive Ban as ecological and other threats are unmanageable;
- Prevent Biopiracy – misuse of DNA sequences created with synbio, under the CBD and Nagoya Protocol;
- Sustainability to minimize synbio's impacts on sustainable biodiversity use.

Defining synthetic biology

An agreed operational definition of synbio is essential as lack of one obstructed CBD and Cartagena Protocol work, impeding risk assessment of synbio applications. We support the AHTEG's synbio definition, as it is appropriately broad in scope and scale:

"Synthetic biology is a further development and new dimension 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."

The Commonwealth Health Department's on-going five-year review of the national Gene Technology Scheme, Phase 3 Preliminary Findings³, say:

"Finding 4: The Review found that synthetic biology is currently within the scope of the

² Katherine Wilson, Could WA be the genetic testing ground for 'synthetic mice' to end mice? SMH, 24 February 2018. <https://www.smh.com.au/environment/conservation/could-wa-be-the-genetic-testing-ground-for-synthetic-mice-to-end-mice-20180221-h0wev9.html>

³ Australian Health Department, Gene Technology Scheme, Phase 3 Preliminary Findings. <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review#phase-3>

Scheme, and there is a high degree of support for this to continue.”

While that finding may be helpful, it continues:

“Work is currently being undertaken by the Australian Council of Learned Academies (ACOLA) which may further inform this issue going forward, including determining the most appropriate mechanism(s) to ensure the appropriate level of regulation of synthetic biology is applied.”

But ACOLA’s work is not open or transparent and Gene Ethics’ approaches to the Committee Chair are ignored.

We also have concerns over conflicts of interest among some expert advisors to the Health Department Review.

Likewise, we adamantly reject self-serving CropLife and company claims that a synbio definition is not needed as the techniques change constantly. The Australian Government must reject this blatant ploy to justify deregulation, in all international negotiations.

Cartagena Protocol

The Australian government should prioritise signing and ratifying the Cartagena Protocol so the nation can fully participate in the Protocol’s work, the Biosafety Clearing House, and the CBD. This should be seen as an essential part of Australia’s Biosecurity protection measures.

CropLife aligned criticisms from outside the Treaty harm the Australian Government’s credibility with the 171 Parties, especially member nations in our region. With over fifteen years experience since the Protocol came into force, claims that it may be used to put up non-tariff barriers to trade are refuted. The Protocol has served the community of nations well, helping to ensure the safe international transfer, handling and use of GMOs, minimizing environmental and public health risk.

The Cartagena Protocol covers some direct biodiversity risks that synthetic organisms pose. However, some important gaps in the Cartagena Protocol prevent achievement of some CBD (Goals 1 and 3) objectives:

- sustainable use of the components of biological diversity;
- fair and equitable sharing of the benefits arising from utilisation of genetic resources.

Economic and other impacts

The CBD requires ongoing processes to minimize synbio impacts on the sustainable use of biodiversity, including socio-economic costs. There are no clear forums for parties to raise and assess synbio impacts, especially the indirect impacts of synbio organisms produced and released. This is despite protocols in the CBD to evaluate the direct biosafety impacts of GMOs on biodiversity (Cartagena Protocol) and for access and benefit-sharing deals (Nagoya Protocol)

But indirect effects and sustainable use impacts can result, for instance, when synbio products replace natural ones, affecting land management practices and loss of sustainable livelihoods. Socio-economic impacts can have serious biodiversity implications. Some AHTEG members say:

“Another aspect of the relationship between synthetic biology and biological diversity that was noted was its potential positive and negative indirect effects, which also have to be taken into account in the adoption and use of organisms, products and components of synthetic biology in order to ensure that the sustainable use of biodiversity is maintained.”
(p5 para 30)

Parties should assess socioeconomic and indirect impacts of synbio products, especially for impacts on sustainable use e.g. Madagascar may see the biosynthesis of a natural commodity (e.g. synbio vanillin replacing vanilla grown in rainforests) affect sustainable use of its natural resources. So a body, process or mechanism is needed where a country may raise concerns and seek redress. Making synbio a standing item in the CBD or sustainable use work may assist.

The CBD and its Protocols have been the prime forums for work on how biotech may affect the living world, for over two decades. New GM techniques e.g. CRISPR, DNA synthesis and gene drives, may radically increase GMO's impacts on biodiversity. So up to date, relevant, international governance arrangements are essential. But GM and agrichemical industries try to frame new GM techniques and their products as exempt from existing rules and definitions. This deregulatory gambit should not succeed as the hazards new GM poses are the same as their forerunners.

The program of synbio work in SBSTTA and the CBD is the only broad international process available to assess synbio's impacts and manage its risks. Unless Parties to the CBD and its Protocols can agree an operational definition for synbio and work to address the most urgent implications, the world may travel into a dangerous new future without appropriate governance to ensure safety and redress.

A process to monitor synbio innovations and deployments is needed. The Biosafety Clearing House should have this as a core part of its work, which needs to be publicly accessible and inclusive of indigenous community representatives.

Invasive organisms and gene drives

The Australian Department of the Environment should advocate in the government and publicly for a moratorium on all field trials or general release of organisms containing gene drives. Harm and containment are prime issues.

Gene drives are designed to deliver a deleterious trait through an entire population of organisms – animals, plants, insects, microbes - potentially driving entire populations or whole species to extinction, or greatly reducing their numbers. This is an extremely high-risk use of synbio techniques. Yet proposals for the environmental release of gene drives in organisms such as rodents⁴, cats⁵ and fish⁶ are already discussed and planned in Australia.

The term 'gene drive' refers to a GM technique that ensures a trait is passed on to 100% of an organism's progeny, rather than a lower percentage inheriting it. So a gene drive's effect is to disseminate the trait through an entire population of organisms. Thus, gene drives are a means for species-wide population engineering. Organisms with short reproduction times (e.g. insects, parasites or pathogens) may be made intentionally extinct, altering entire ecosystems so quickly that they may not have enough time to reconfigure, with other unforeseen knock on effects.

Such organisms may also travel globally, through inadvertent or deliberate transmission, to where the target organism is a benign native, essential to ecosystem integrity. Environmental, human food security and social stability impacts may be very widespread and their impacts are not yet assessed.

The first CRISPR gene drive system, only invented in 2014, has been replicated multiple times. Gene drive organisms are proposed for field trial release in Africa, USA, and on Australian islands with US military funding.⁷

Target Malaria is one consortium that proposes to field trial gene drive mosquitoes in central Africa, to attack the microbial vector for malaria. A US group Island Conservation proposes to

⁴ Ibid. Wilson 2018.

⁵ Greg Bearup, Gene war strategy to rub out feral cats, The Weekend Australian, The Nation 9, May 26-27, 2018.

⁶ Dr Ron Thresher, Daughterless fish technology, CSIRO Marine.
<http://www.invasiveanimals.com/research/phase1/goals/goal-4/4f3/>

⁷ Op cit. Wilson 2018.

release gene-drive mice into island ecosystems by 2020 as a biological control method to attack invasive mice. Avian malaria mosquitoes are the targets for gene drive research in Hawaii.

Several strong warnings have been issued against using gene drives. An article in Nature that gene drive developers authored, explained the risk of unintended ecological impacts and malicious use of gene drive systems.⁸ In November 2015, the AHTEG on Synthetic Biology found gene drives to be a threat that may also disrupt achieving the CBD's goals:

“Applications that are aimed at altering and replacing natural populations (for example, gene drive systems) may have adverse effects at the ecosystem level, and vis-à-vis the other two objectives of the Convention”

UNEP/CBD/SYNBIO/AHTEG/2015/1/3 - p9

The US National Academy of Sciences in 2016 issued a 200-page report on gene drive governance, noting the need for precaution and thorough ecological assessments as “there is insufficient evidence available at this time to support the release of gene-drive modified organisms”⁹. NAS also saw the CBD as the main international regulatory forum to find solutions.

We support the International Union for Conservation of Nature (IUCN) program of work laid out in document IUCN WCC-2016-Res-086-EN¹⁰ and encourage the Department of Environment to adopt a similar approach. In September 2016, government and civil society members of (IUCN) passed a motion calling for a de facto moratorium on any support or funding towards gene drive research or deployment. IUCN membership:

“Calls upon the Director General and Commissions with urgency to assess the implications of gene drives and related techniques and their potential impacts on the conservation and sustainable use of biological diversity as well as equitable sharing of benefits arising from genetic resources, in order to develop IUCN guidance on this topic, while refraining from supporting or endorsing research, including field trials, into the use of gene drives for conservation or other purposes until this assessment has been undertaken.”¹¹

Concurrently, a statement from 30 conservation and environmental leaders (including Dr Jane Goodall, Dr David Suzuki and Dr Vandana Shiva) called for gene drives not to be promoted as conservation tools:

“Given the obvious dangers of irretrievably releasing genocidal genes into the natural world, and the moral implications of taking such action, we call for a halt to all proposals for the use of gene drive technologies, but especially in conservation”¹²

The Australian Department of Environment and Government should back precaution and a moratorium on release or field trialing of all gene drive systems.

The proposals of groups like Australian Wildlife Conservancy and CSIRO¹³ and Island Conservation, to use gene drives for biocontrol of invasive species, should be discouraged.

⁸ Oye, K.A. *et al.* (2014). Regulating gene drives, *Science*. **345(6197)**: 626–628.

⁹ "Gene Drive Research in Non-Human Organisms: Recommendations for Responsible Conduct". *National Academies of Sciences, Engineering, and Medicine*. June 8, 2016.

¹⁰ Development of IUCN policy on biodiversity conservation and synthetic biology, IUCN WCC-2016-Res-086-EN. https://portals.iucn.org/library/sites/library/files/resrecfiles/WCC_2016_RES_086_EN.pdf

¹¹ <https://portals.iucn.org/congress/motion/095/18902>

¹² http://www.etcgroup.org/sites/www.etcgroup.org/files/files/final_gene_drive_letter.pdf

¹³ Greg Bearup, Gene war strategy to rub out feral cats, *The Weekend Australian*, *The Nation* 9, May 26-27, 2018.

As the US National Academy of Sciences noted:

“Because gene-drive modified organisms are intended to spread in the environment, there is a widespread sense among researchers and commentators that they may have harmful effects for other species or ecosystems. For example, using a gene drive to suppress a non-native weed population may lead to unexpected consequences, such as the loss of habitat for native species or even the establishment of a second, more resilient invasive species.”

Digital transfer

The sequencing and synthesizing of DNA enables ‘digital’ biopiracy, so access and benefit sharing rules may be flouted. Parties should agree to digital sequence processing being urgently resolved with SBSTTA, and Parties to the Nagoya Protocol cooperating.

Powerful new GM techniques that comprise synbio, such as CRISPR, facilitate biopiracy and may jeopardize the CBD's and Nagoya Protocol's access and benefit sharing obligations being implemented. Genetic resources such as microorganisms may be digitally encoded, transferred and synthesized into living matter without any physical transmission of biological material.

As many more genetic resources are sequenced, transferred, and digitally stored, the Convention must carefully study the implications, to develop policy that defends the Convention's objective of fair and equitable benefit sharing of genetic resources.

Developing countries, farmers' organizations, and civil society see threats in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) programs which host "big data" sequencing projects such as DivSeek.

The CBD must take a lead role in protections to ensure that digital sequence information and gene editing are not used to promote biopiracy. A clear and strong position from the CBD is key as it may assist WHO, ITPGRFA, and other institutions to resolve biopiracy issues as they arise. A prompt start in the Synthetic Biology AHTEG would assist developing country Parties to the CBD.

The cultivars and wild relatives of crop plants that DivSeek is targeting for mass genome sequencing should fall under CBD and Nagoya rules. But companies may access and analyse the data produced, alienating the developing countries key genetic diversity, without ever signing an access and benefit sharing agreement.

As sequencing improves and technologies like "sequence in place" become a reality – allowing small or even handheld devices to quickly sequence samples and distribute the result – tomorrow's biopirate will have no need to smuggle biological samples across national, physical borders. The data can be stored on a memory card and transmitted, or uploaded to the cloud.

Bob Phelps, Executive Director, 31 May, 2018.