Note - The Synthetic Biology Revolution: Mapping A Future Research Agenda

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Abstract

Synthetic biology represents a startling and perhaps revolutionary development in the biosciences with significant implications for the future of biotechnology and its interface with international environmental law. This article identifies the challenges the synthetic biology revolution poses for international environmental law and sets out key research questions for the future. The note opens by first examining how synthetic biology differs from GMO's and provides a brief insight into the current scale of research and development relating to synthetic biology and the focus of its recent developments. Beyond that the article then goes on to highlight some of the key environmental risks associated with this revolutionary technology. The note examines the emerging debates surrounding synthetic biology in the forums associated with the 1992 *United Nations Convention on Biological Diversity*. Finally, the note concludes with a brief comment on the need for responses shaped under international environmental law to also be linked to developments in other areas of law especially laws dealing with weapons proliferation and terrorism.

I INTRODUCTION

Synthetic biology represents a startling and perhaps revolutionary development in the biosciences with significant implications for the future of biotechnology and its interface with international environmental law. At a simplistic level, the concept of synthetic biology boils down to one key hypothesis: that life or the components of life can be designed on a computer, chemically made in the laboratory and then transplanted into cells to create new life forms. The profound possibilities of this technology were most vividly demonstrated in 2010 when researchers at the J Craig Venter Institute announced 'the successful construction of the first self-replicating, synthetic bacterial cell'; that they had 'synthesised the 1.08 million base-pair chromosome of a modified *Mycoplasma mycoides* genome'; and that this was 'the proof of principle that genomes

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can be designed *in silico* (in the computer), chemically produced in the laboratory and transplanted into a recipient cell to produce a new self-replicating cell controlled only by the synthetic genome.'[1]

Synthetic biology is far more complex than just this one scientific claim. It does appear that synthetic biology is a totally new area of biological research and involves fundamentally different techniques from those used in creating genetically modified organisms (GMOs). These revolutionary developments in the biosciences and the biotechnology industry are only just beginning to be understood in policy and legal circles. There has in fact been little analysis of the legal implications of synthetic biology in terms of the potential implications for the environment.

This note presents a preliminary sketch of some of the key legal issues relating to synthetic biology and emerging responses under international environmental law. It does not aim to be a definitive analysis of the challenges posed, nor does it purport to offer a comprehensive or preferred model for a response to these challenges. Rather, it seeks to alert environmental lawyers to these challenges and map out a research agenda for this issue into the future.

The note proceeds in part II by first examining how synthetic biology differs from GMO's and provides a brief insight into the current scale of research and development relating to synthetic biology and the focus of its recent developments. Part III then goes on to highlight some of the key environmental risks associated with this revolutionary technology. Part IV then examines the emerging debates surrounding synthetic biology in the forums associated with 1992 *United Nations Convention on Biological Diversity.*[2] The note concludes with a brief comment on the need for responses shaped under international environmental law to also be linked to developments in other areas of law, especially laws dealing with weapons proliferation and terrorism.

II How Is Synthetic Biology Different From GMO's?

Synthetic biology comprises the purposeful creation of totally new organisms piece by piece.[3] By contrast, GMOs are produced by transferring individual genes from one species to another. In a recent

[1] J Craig Venter Institute, *Press Release-First Self Replicating Synthetic Biological Cell* (20 May 2010) <http://www.jcvi.org/cms/press/press-releases/full-text/article/first-self-replicating-synthetic-bacterial-cell-constructed-by-j-craig-venter-institute-researcher/>. See also Daniel Gibson et al, 'Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome' (2010) 329(5987) *Science* 52-56.

[2] *United Nations Convention on Biological Diversity*, opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993).

[3] Gregory Mandel, *Regulating Emerging Technologies* (Research Paper No 2009-18, Temple University School of Law, 9 March 2009).

study prepared for the European Commission, synthetic biology was described as:

> engineering of biology: the synthesis of complex, biologically-based (or inspired) systems which display functions that do not exist in nature. This engineering approach may be applied at all levels of the hierarchy of biological structures – from individual molecules to whole cells, tissues and organisms.[4]

The US Presidential Commission on the Study of Bioethical Issues explained synthetic biology in the following terms:

> Synthetic biology is the name given to an emerging field of research that combines elements of biology, engineering, genetics, chemistry, and computer science. The diverse but related endeavors that fall under its umbrella rely on chemically synthesized DNA, along with standardized and automatable processes, to create new biochemical systems or organisms with novel or enhanced characteristics. Whereas standard biology treats the structure and chemistry of living things as natural phenomena to be understood and explained, synthetic biology treats biochemical processes, molecules, and structures as raw materials and tools to be used in novel and potentially useful ways, often quite independent of their natural roles. It joins the knowledge and techniques of biology with the practical principles and techniques of engineering. "Bottom-up" synthetic biologists, those in the very earliest stages of research, seek to create novel biochemical systems and organisms from scratch, using nothing but chemical reagents. "Top-down" synthetic biologists, who have been working for several decades, treat existing organisms, genes, enzymes, and other biological materials as parts or tools to be reconfigured for purposes chosen by the investigator.[5]

This new approach has emerged as a consequence of rapid developments in genomics, a field of science which results from 'a marriage of molecular and cell biology with classical genetics' and computing science.[6] This is different from more traditional approaches to biotechnology research, development and commercialisation over recent decades. Historical developments in international environmental law have been premised on the assumption that biotechnology research and development followed a predictable and linear process: scientists collected samples of wild genetic resources in the field, returned these samples to their laboratories where they were systematically screened for

[4] European Commission, *Synthetic Biology: Applying Engineering to Biology* (Report No EUR 21796, NEST High-Level Expert Group, 2005) 5.
[5] Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (Washington, 2010) 36.
[6] Miguel García-Sancho, 'Mapping and Sequencing Information: The Social Context for the Genomics Revolution' (2003) 31(1) *Endeavour* 18, 21.

possible leads for new developments in biotechnology.[7] New drugs and (other products) were developed subsequently, through a process of trial and error.

While these assumptions underlie much of the current international environmental law, in reality biotechnology research, development and commercialisation is a far more complex process.

Since the mid-1980s the emergence of revolutionary technologies such as gene sequencing and database mining driven by the power of bioinformatics enabled rapid screening of possible leads and hence major developments in biotechnology.[8] This new era of collective intelligence[9] is characterised by the sharing of data through massive online databases.[10] Access to data and computing is now integral to biotechnology research, development and commercialisation, and is fast eclipsing access to samples of specific species collected from the wild as a major driver in biotechnology innovation.[11]

Synthetic genomics takes the marriage of biology and computing beyond simply understanding molecular and cell biology. It makes it possible to actually construct the building blocks of life from scratch. As Garfinkel and Friedman have explained, synthetic genomics is a 'set of technologies that make it possible to construct a molecule of DNA of any specified sequence and nearly any length, up to the size of a whole genome.'[12] Through the assembly of DNA molecules, individual genes, chromosomes and even whole genomes can be created.[13] This opens the possibility of redesigning existing organisms and even the 'de novo design and 'programming' of genes and organisms.'[14]

As an emerging field there are several different approaches, but the most dominant of these borrows heavily from the engineering concept of

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[7] David Leary and Kim Juniper, 'Addressing the Marine Genetic Resources Issue: Is the debate heading in the wrong direction?' in Clive Schofield. Seokwoo Lee and Moon-Sang Kwon, *The Limits of National Jurisdiction* (Martinus Nijhoff, 2014), 769-785.
[8] Ibid.
[9] Eric Bonabeau, 'Decisions 2.0: The Power of Collective Intelligence' (2009) 50(2) *MIT Sloan Management Review* 45.
[10] For an overview of the growth of databases, bioinformatics and the central role of date in modern research and development see Elsevier, *Encyclopedia of Microbiology* (at 2009) 'Genome Sequence Databases: Types of Data and Bioinformatic Tools', 211-236.
[11] Ibid.
[12] Michele Garfinkel and Robert Friedman, 'Synthetic Biology and Synthetic Genomics' in David Leary and Balakrishna Pisupati (eds), *The Future of International Environmental Law* (United Nations University Press, 2010) 269, 270.
[13] Gabrielle Samuel, Michael Selgelid and Ian Kerridge, 'Managing the Unimaginable. Regulatory Responses to the Challenges Posed by Synthetic Biology and Synthetic Genomics' (2009) 10(1) *EMBO Reports* 7.
[14] Andrew Torrance, 'Synthesizing Law for Synthetic Biology' (2010) 11(2) *Minnesota Journal of Law, Science & Technology* 629.

modularity, which suggests that all complex living entities can be broken down into their respective component functional modules.[15] For the biosciences an approach premised on modularity suggests that if biologically complex organisms can be broken down into their constituent modules, then in theory, they can be reassembled as totally novel biological structures and ultimately life forms.

As Calvert has observed, such an approach

> not only makes biological complexity easier to deal with, but also makes these components more similar to software code which is modular, standardised and reusable.[16]

III THE FOCUS OF SYNTHETIC BIOLOGY R&D IN THE BIOTECHNOLOGY SECTOR

The science of synthetic biology is gradually being incorporated into mainstream biotechnology research and commercial development. There has been a significant increase in entities conducting research relating to synthetic biology from 2009 to 2013.[17] A total of 508 unique entities conducting research on synthetic biology have been identified globally including more than 192 biotechnology companies and 204 universities across the world.[18] Much of this research and development is occurring at universities, government research institutions and military laboratories in the USA and Europe.[19] There is also a growing body of research and development occurring in countries such as Japan, China, India, Israel, South Africa, Brazil and Australia.[20] Corporate entities involved in synthetic biology research and development globally include drug manufacturers Merck Serono (a division of the Merck Group of companies), industrial companies such as Goodyear Tyre and Rubber, University research spin off and small scale biotech start-up companies.[21]

Areas of interest for large scale research and development overseas have included the development of 'new biological production techniques for existing or novel biological materials and chemicals, including food ingredients and biofuels' as well as 'new and improved diagnostics, drugs

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[15] Jane Calvert, 'The Commodification of Emergence: Systems Biology, Synthetic Biology and Intellectual Property' (2008) 3(4) *BioSocieties* 385-400.
[16] Ibid.
[17] Wilson Centre Synthetic Biology Project, *Tracking the Growth of Synthetic Biology for 2013* <http://www.synbioproject.org/inventories/maps-inventory/>.
[18] Ibid.
[19] Ibid.
[20] Ibid.
[21] Ibid.

and vaccines.'[22] A key focus in the later is on developing new treatments for diabetes and malaria.[23] One of the most advanced areas is synthetically engineering an alternative to Artemisinin – a naturally occurring anti-malarial drug. In 2011 drug manufacturer Sanofi began large scale manufacture of semi-synthetic artemisinin in Italy.[24] The production of this drug using the techniques of synthetic biology is expected to reduce the costs of manufacturing by a factor of 10.[25] Other areas of ongoing research include the development of new tools for bioremediation and biosensors for use in areas such as detecting contamination in drinking water.[26]

IV MANAGING SYNTHETIC BIOLOGY RISKS: CURRENT REGULATORY APPROACHES

Synthetic biology has raised a series of social, ethical, philosophical, theological and moral issues which a significant body of academic literature has already engaged with.[27] This is due in large part to the way this technology has the potential to challenge entrenched philosophical 'distinctions between, amongst others, life and non-life, the natural and the artificial, the evolved and the designed, and even the material and the informational' leading inevitably to accusations that researchers are playing god or even 'treading in Frankenstein's footsteps'.[28] Extending Foucault's work on biopolitics, legal scholars have already made valuable contributions to the ongoing philosophical debates concerning synthetic biology.[29]

While intellectually these debates are interesting and will continue, this aspect of synthetic biology has already been widely canvassed in the academic literature.[30] There is also an extensive body of literature that

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[22] Parliamentary Office of Science and Technology, *Postnote: Synthetic Biology* (January 2008) <http://www.parliament.uk/documents/post/postpn298.pdf>.
[23] Trichi Saukshmya and Archana Chugh, 'Commercializing Synthetic Biology: Socio-Ethical Concerns and Challenges Under Intellectual Property Regime' (2010) 16(2) *Journal of Commercial Biotechnology* 135.
[24] Sanofi and PATH, 'Sanofi and PATH announce the Launch of Large-scale Production of Semisynthetic Artemisinin against Malaria' (Press Release, 11 April 2013) <http://en.sanofi.com/Images/32474_20130411_ARTEMISININE_en.pdf>.
[25] Markus Schmidt, 'Diffusion of Synthetic Biology: A Challenge to Biosafety' (2008) 2 *Systems and Synthetic Biology* 1.
[26] Parliamentary Office of Science and Technology, above n 22.
[27] See for example Paul Rabinow, 'Prosperity, Amelioration, Flourishing: From a Logic of Practical Judgment' (2009) 21(3) *Law and Literature* 301; Gary Edmond and David Mercer, 'Norms and Irony in the Biosciences: Ameliorating Critique in Synthetic Biology' (2009) 21(3) *Law and Literature* 445.
[28] Henk van den Belt, 'Playing God in Frankenstein's Footsteps: Synthetic Biology and the Meaning of Life' (2009) 3 *Nanoethics* 257.
[29] See, for example, above n 27.
[30] Ibid.

deals with the implications of synthetic biology for intellectual property rights.[31] In contrast, studies of risks posed to biosafety, human health and biodiversity have largely been lacking and demand closer attention. Lawyers, and environmental lawyers in particular, should now focus on the practical challenges and potential risks to biosafety, human health and biodiversity which are posed by developments in synthetic biology.

Most obviously, concerns have been raised that synthetic organisms could escape from a research laboratory or containment facility and cause damage to the environment or threaten human or animal health.[32] It is foreseeable that a synthetic microorganism developed for a particular purpose might also cause harmful side effects when deliberately released into the environment.[33] Also as Bhutkar has suggested,[34] '[a]ny genetic exchange between a synthetic biological entity and a naturally occurring biological entity would result in natural genome contamination.'[35]

Internationally there is an emerging debate as to whether existing regulation of biotechnology can adequately respond to the environmental concerns raised in relation to synthetic biology, and in particular whether it is caught by the current regulation. However, the literature that has examined the potential environmental and biosafety risks to date has come almost exclusively from the scientific community and has not benefited from robust legal analysis.

For example, one of the most widely cited studies so far which examines regulatory options for synthetic biology was written by scientists active in synthetic biology research with close links to the J Craig Venter Institute.[36] Most of these have indicated a series of options for governance with an emphasis on self-regulation. Implicit in a preference for self-regulation is the assumption that existing regulatory frameworks for biotechnology already function effectively to manage risks. A second assumption is that biotechnology involving synthetic biology is essentially the same as other forms of biotechnology. Therefore if

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[31] See for example Arti Rai and James Boyle, 'Synthetic Biology: Caught Between Property Rights, the Public Domain and the Commons" (2007) 5(3) *PLoS Biology* 5(3), e58; Jane Calvert, 'The Commodification of Emergence: Systems Biology, Synthetic Biology and Intellectual Property' (2008) 3 *Biosocieties* 383; Andrew Torrance, 'Synthesizing Law For Synthetic Biology' (2010) 11(2) *Minnesota Journal of Law, Science & Technology* 629

[32] Jonathan Tucker and Raymond Zilinskas. 'The Promise and Perils of Synthetic Biology' (2006) 12 *The New Atlantis. A Journal of Technology & Society* 25.

[33] Ibid.

[34] Arjun Bhutkar, 'Synthetic Biology: Navigating the Challenges Ahead.' (2005) 8(2) *Journal of Biolaw & Business* 19.

[35] Ibid.

[36] See Michele Garfinkel et al, 'Synthetic Genomics: Options for Governance' (2007) 5(4) *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 359-62.

existing regulation works for other areas there is no need to consider further regulatory or legislative intervention.

No detailed study has considered whether existing international regulation does effectively manage these risks. The studies that do exist are exclusively focussed on the North American or European domestic contexts and have lacked sufficient detailed legal analysis. For example, the US Presidential Commission for the Study of Bioethical Issues established by President Obama noted the existence of a 'patchwork quilt' of regulatory measures in the United States, but called for a 'more comprehensive review' to be undertaken to ensure these measures are adequate into the future.[37]

Similarly the European Academies Science Advisory Council has recommended that the European Commission consider the need for regulatory reform in light of developments in synthetic biology.[38] Likewise the OECD Working Party on Biotechnology is currently looking at governance and regulatory structures for biotechnology including the role of synthetic biology 'in the bio-economy, the necessary infrastructure and challenges to its development'.[39]

V THE EMERGING DEBATE IN INTERNATIONAL ENVIRONMENTAL LAW

There has been little consideration of the relevance of international environmental law to addressing concerns associated with synthetic biology, but what debate there has been has largely been confined to considering the relevance of the 1992 *United Nations Convention on Biological Diversity*[40] ('*CBD*') and its associated protocols.

The *CBD* and, more recently, its 2010 *Nagoya Protocol*[41] explicitly recognise the important role biodiversity has played in the development of biotechnology by acknowledging the sovereignty of nation states over their genetic resources and in its recognition of the importance of the conservation and sustainable use of the components of biodiversity. A

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[37] Presidential Commission for the Study of Bioethical Issues, above n 5, 102.

[38] European Academies Science Advisory Council, 'Realising Potential in Synthetic Biology: Scientific Opportunities and Good Governance' (Policy Report No 13, December 2010).

[39] Organisation for Economic Co-operation and Development, *Biotechnology Update:* (Newsletter No 25, Internal Co-ordination Group for Biotechnology (ICGB), 6 June 2013) 18 <http://www.oecd.org/env/ehs/biotrack/Biotech_Update_No25_6June2013.pdf>.

[40] *United Nations Convention on Biological Diversity*, opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993).

[41] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, opened for signature 29 October 2010, UN Doc UNEP/CBD/COP/DEC/X/1 (entered into force 12 October 2014).

key feature of the *CBD* and the *Nagoya Protocol* is the way it regulates access to such resources and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Subsequent to the adoption of the *CBD,* the Conference of Parties of the CBD adopted the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*[42] ('*Cartagena Protocol*') and the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*[43] ('*Supplementary Biosafety Protocol*').

The *Cartagena Protocol* grew out of the emergence of GMO's which arose from the application of new scientific research and development techniques in biotechnology research, development and commercialisation. As Sands notes the emergence of GMO's raised significant challenges for the regulation of biotechnology and in particular the

> appropriate balance to be struck between the objectives of ensuring, on the one hand, that developments in the field of biotechnology do not cause adverse effects for human health and the environment and, on the other hand, that new international regulatory arrangements do not place undue limits on the development, dissemination and use of biotechnology.[44]

This is precisely the same balancing act that must be weighed up when considering synthetic biology. Today the transformative potential of synthetic biology to our lives and the world is in its infancy. But policymakers need to effectively balance management of risks to biosafety, human health and the environment with a regulatory environment that encourages innovation in the growing global biotechnology sector.

The existing international law embodied in the *Cartagena Protocol* seeks to strike a balance between these two objectives by ensuring an adequate level of regulation of potential adverse effects on the conservation and sustainable use of biological diversity, and risks to human health during the trans-boundary movement of GMO's across international borders. It does this by prescribing a regulatory regime relating to the safe transfer, handling and use of GMO's based on an advanced informed agreement

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[42] *Cartagena Protocol on Biosafety to the Convention on Biological Diversity,* opened for signature 29 January 2000, 2226 UNTS 208 (entered in force 11 September 2003).
[43] *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, opened for signature 16 October 2010, UN Doc UNEP/CBD/BS/COP-MOP/5/17 (not yet in force).
[44] Phillippe Sands, *Principles of International Environmental Law* (Cambridge University Press, 2nd ed, 2003), 652.

procedure, which governs the trans-boundary movement and intentional introduction into the environment of the recipient state.[45]

However, it is unclear to what extent both the *CBD* and the *Cartagena Protocol* apply to synthetic biology. Oldham, Hall and Burton[46] have highlighted six key issues that warrant further detailed study including:

- the implications of the increased reliance on digital information and the ease by which it can transmitted, reproduced and manipulated in biotechnology research, and what this may mean for the future relevance of the access and benefit sharing provisions of the *CBD* and the *Nagoya Protocol,* and the impact this may have on developing countries;
- the relevance of the precautionary principle embedded in the CBD and the *Cartagena Protocol*;
- problems with the application of the *Cartagena Protocol*, given scientific techniques involved in synthetic biology research and development in the context of biotechnology development fall outside the scope of the definition of 'modern biotechnology' in Article 3(i) of *Cartagena Protocol,* and therefore outside of the definition of 'living modified organism' under Article 3(g);
- the fact that the *Cartagena Protocol* does not apply to material or digital transfers of genetic sequences, components and parts, particularly important as biotechnology research and development is increasingly dependent on data and computing technology;
- the extent to which the various mechanisms, such as the waiver mechanism associated with advanced informed consent procedure relating to trans boundary movements of GMO's under Article 6.2 of the *Cartagena Protocol* and *the Supplementary Biosafety Protocol* apply or not to synthetic organisms; and finally,
- whether these concerns justify an immediate moratorium on the environmental release of synthetic organisms.[47]

Each of these questions merit further detailed study in their own right and should form the core of a research agenda on the ability of the existing international environmental law to sustainably manage developments in

[45] *Cartagena Protocol*, arts 7-9, 11-12.
[46] Paul Oldham, Stephen Hall and Geoff Burton*, Synthetic Biology: Mapping the Scientific Landscape* (2012) 7(4) *PLoS One* 1, 12-14.
[47] Ibid.

synthetic biology in the biotechnology sector. Further detailed analysis may reveal other gaps.

As a starting point I suggest the following questions need to be examined: Firstly, what novel risks does synthetic biology pose to the environment and human health beyond those already regulated under the existing law? Secondly, do the provisions of the Cartagena Protocol apply to the products of synthetic biology? Thirdly are existing approaches to risk management embodied in the current law adequate for regulating biosafety risks associated with synthetic biology? Finally, does the existing law place sufficient restrictions on the development of this technology to prevent accidental or malicious release of synthetic organisms?

A robust legal analysis should also consider what other sources of international environmental law (including existing treaty regimes, customary international law and soft law) are relevant to regulating synthetic biology. It is from that point that we can then go on to examine what options there are for addressing these gaps.

Beyond the academic literature debate is beginning to emerge within the forums of the *CBD* and the *Cartagena Protocol* as to the adequacy of these instruments to respond to both the opportunities and emerging concerns relating to synthetic biology.[48] Synthetic biology was first considered by the Subsidiary Body on Scientific Technical and Technological Advice (SBSTTA) of the *CBD* at its 14th meeting in Nairobi in 2010 when the SBSTTA formally invited Parties, other governments and relevant organisations to submit information on synthetic biology while recommending the application of 'the precautionary approach to the field release of synthetic life, cell or genome into the environment'.[49] The issue was subsequently discussed at the 16th meeting of the SBSTTA in Montreal in 2012. The SBSTTA could not agree on a recommendation on how to proceed with the issue and accordingly gave three possible alternate recommendations to the Conference of Parties ('COP') of the *CBD*.

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[48] For example, see, ETC Group, *Synthetic Biology Creating Artificial Life Forms: Briefing and Recommendations For CBD Delegates to COP 10* (ETC Group, October 2010) <http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_COP10SynbioBriefing081010.pdf>; International Civil Society Working Group on Synthetic Biology, Submission to Convention on Biological Diversity's Subsidiary Body on Scientific, Technical and Technological Advice, 15 October 2011 <http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/cbdsynbiocsosubm.pdf>.

[49] Subsidiary Body on Scientific, Technical and Technological Advice to the Convention on Biological Diversity, *Recommendation Adopted by the Subsidiary Body On Scientific, Technical And Technological Advice at its Fourteenth Meeting,* Recommendation XIV/16, 14th mtg, UN Doc UNEP/CBD/SBSTTA/REC/XIV/16 (30 June 2010), para 4.

Subsequently, at its 11th meeting in India in December 2012, the COP made a number of decisions on a way forward for consideration of synthetic biology within the context of the *CBD*. Of particular significance for present purposes was the fact the Executive Secretary was directed by the COP of the *CBD* to prepare a study of 'possible gaps and overlaps with the applicable provisions of the [*CBD*], its protocols and other relevant agreements related to components, organisms and products resulting from synthetic biology techniques' (hereinafter 'the gap analysis').[50] The COP also resolved to invite Parties, other Governments and relevant international organisations, indigenous and local communities to submit 'additional relevant information on components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations' (hereinafter the 'impacts analysis').[51]

A draft of the gap analysis and the impacts analysis was made available to parties of the *CBD* and other interested parties for peer review from July to September 2013. Following that peer review, a further revision of these studies (funded by the United Kingdom) was prepared by the Secretariat of the *CBD* in April 2014 and made available to SBSTTA.[52] These drafts were considered by the SBSTA at its 18th meeting in Montreal in June 2014, and the SBSTTA recommended to the next COP of the CBD that the revised drafts of the gap analysis and the impacts analysis be subject to a further round of peer review.[53]

A detailed review of both the gap analysis and the impacts analysis is not possible for the purposes of this brief note as they are embargoed and not available for citation as at the date of writing. But in future analysis of this issue, I would note in passing that these documents and their analysis warrant close attention. I question the extent to which some of the assertions and conclusions of these papers are actually justified by reference to analysis of the existing law.

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[50] Conference of Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Eleventh Meeting*, Decision XI/11, 11th mtg, UN Doc UNEP/CBD/COP/DEC/XI/11 (5 December 2012), para 3(c).

[51] Ibid para 3(a).

[52] See Subsidiary Body on Scientific Technical and Technological Advice, *New and Emerging Issues Relating to the Conservation and Sustainable Use of Biodiversity*, 18th mtg, UN Doc UNEP/CBD/SBSTTA/18/INF/4 (20 May 2014).

[53] Subsidiary Body on Scientific Technical and Technological Advice, *Report Of The Eighteenth Meeting Of The Subsidiary Body On Scientific, Technical And Technological Advice*, 12th mtg, UN Doc UNEP/CBD/COP/12/3 (28 June 2014) annex 'Recommendations Adopted by the Subsidiary Body on Scientific, Technical And Technological Advice At Its Eighteenth Meeting', recommendation XVIII/7, para 7.

Much of the debate relating to synthetic biology in the forums of the CBD has focussed upon whether synthetic biology is a new or emerging issue that parties to the CBD need to address, and it is this aspect of the issue which has occupied debate at both the SBSTTA and COP of the CBD over the past few years.

Most recently, at the 12th Meeting of the Conference of Parties of the CBD held in Korea in 2014 the COP resolved that there is currently 'insufficient information available ….to decide whether or not [synthetic biology] is a new and emerging issue related to conservation and sustainable use of biodiversity.'[54] Nonetheless the COP also resolved to urge parties and invite other governments to take a precautionary approach to synthetic biology and:

> (a) To establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention;
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> (b) To approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks, as appropriate;
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> (c) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities;
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> (d) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations;
>
> (e) To cooperate in the development and/or strengthening of human resources and institutional capacities, including on methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing countries, in particular the least developed countries and small island developing States, and countries with economies in transition, including through existing

[54] Conference of Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Eleventh Meeting*, Decision XII/24, 12th mtg, UN Doc UNEP/CBD/COP/DEC/XII/24 (17 October 2014) para 1.

> global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard.[55]

Perhaps more significantly the COP also agreed to establish an Ad Hoc Technical Expert Group composed of indigenous and local communities and all relevant stakeholders, including other Governments, with knowledge of the Convention and its Protocols with the following terms of reference:

(a) Take note of the exchange of views on how to address the relationship between synthetic biology and biological diversity;

(b) Identify the similarities and differences between living modified organisms (as defined in the *Cartagena Protocol*) and organisms, components and products of synthetic biology techniques to determine if living modified organisms derived from synthetic biology fall under the scope of the *Cartagena Protocol*;

(c) Identify if other national, regional and/or international instruments adequately regulate the organisms, components or products derived from synthetic biology techniques in so far as they impact on the objectives of the *Convention* and its Protocols;

(d) Work towards an operational definition of synthetic biology, comprising inclusion and exclusion criteria, using all relevant information, based on scientific and peer-reviewed studies;

(e) Identify the potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols;

(f) Building on the work on risk assessment and risk management undertaken by the Cartagena Protocol, compile information on best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes and to help those Parties and other Governments to regulate organisms,

[55] Ibid para 3.

components and products from synthetic biology techniques appropriately;

(g) Identify if the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.[56]

While not yet formally recognised as a new emerging issue by the COP of the *CBD*, it is nonetheless clear from the terms of reference of the Ad hoc experts group that it is recognised by State Parties that this is an issue meriting robust and detailed consideration by the international community over coming years. Any future research by scholars of international environmental law on these questions would be useful to inform debate at the forums of the *CBD*.

VI Responding To Synthetic Biology And The Problem Of The Fragmentation Of International Law

One of the contemporary challenges for international environmental law is how it has become fragmented and disconnected from other areas of international law.[57] International environmental law has increasingly been regarded by practitioners, academics and policy makers alike as a discrete body of law separate from other areas such as, for example international trade law or human rights law. But this failure to recognise linkages with other areas of international law has also undermined the effectiveness of international environmental law.[58]

While synthetic biology poses new challenges for international environmental law, it is clear that we cannot just consider this an issue relating to international environmental law alone and the challenges of fragmentation need to be kept in mind as international environmental law relating to synthetic biology is developed.

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[56] Ibid annex.

[57] This has been discussed extensively in the literature. See for example Edith Brown Weiss, 'New Directions in International Environmental Law' (speech delivered at United Nations Congress on Public International Law, New York, 1995) reproduced in Donna G Craig, Nicolas A Robinson and Koh Kheng-Lian, *Capacity Building for Environmental Law in the Asian and Pacific Region:* (Asian Development Bank, 2002) vol 1, 10-11; William Bradnee Chambers, *Interlinkages and the Effectiveness of Multilateral Environmental Agreements* (United Nations University, 2008); Philippe Sands et al, *Principles of International Environmental Law* (Cambridge University Press, 3rd ed, 2012), 893-895.

[58] Ibid.

For present purposes, the most significant area that needs to be considered is international law relevant to bioterrorism. The dual use nature of synthetic biology means that as well as creating new biological structures or organisms for beneficial purposes such as new drugs or biofuels, it also has significant potential use for terrorist purposes. This potential has already been demonstrated with the synthesis of several pathogenic viruses, such as an infectious poliovirus and a synthetic form of the virus responsible for the 1918 influenza pandemic.[59]

The availability of DNA sequence data and molecular biology techniques on the internet, along with the fact that specially synthesized DNA can easily be purchased from specialised companies, make it possible for actors with malevolent intent to engineer a virus that could be used in a terrorist attack.[60] Beyond deliberate acts of terrorism, as biology increasingly becomes influenced by engineering or informational approaches it has also been suggested it will not be long before computer scientists and/or hackers could turn their interest to synthetic biology.[61]

Given the implications of synthetic biology for bioterrorism it is important therefore that any future developments in international environmental law be informed by international and national legal developments relating to bio-terrorism. The focus of ongoing and future developments in relation to synthetic biology in the forums of the *CBD* will not be on bioterrorism and dual use per se, but options for international environmental law reform in relation to the biosafety, human health and biodiversity implications of synthetic biology will need to be nested in an understanding of the concerns surrounding the dual use implications of the technology.

In the field of bio-terrorism law the most important developments have taken place in the context of the 1972 *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* ('*BTW Convention*').[62] The *BTW Convention* bans the development, production, stockpiling, acquisition and retention of microbial or other biological agents or toxins, in types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.[63] Pursuant to the

[59] Joyce Tait, 'Governing Synthetic Biology: Processes and Outcomes' in Markus Schmidt et al (eds), *Synthetic Biology: The Technoscience and its Societal Consequences* (Springer, 2009) 141-154.
[60] Garfinkel and Friedman, above n 12, 269-291.
[61] Markus Schmidt, 'Diffusion of Synthetic Biology: A Challenge to Biosafety' (2008) 2(1-2) *Systems and Synthetic Biology* 1.
[62] *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxic Weapons, and on their Destruction*, opened for signature 10 April 1972, 1015 UNTS 163 (entered into force 28 March 1975).
[63] *BTW Convention*, art 1(1).

BTW Convention, States are required to legislate to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery banned under the *BTW Convention*, within their territory, jurisdiction or control.[64]

Operating in parallel to the *BTW Convention* the so-called 'Australia Group' of countries is an informal association of countries that aim to minimize the risk of further proliferation of chemical and biological weapons.[65] In 2008, the Australia Group agreed to form a synthetic biology advisory body to keep informed of developments in relation to synthetic biology relevant to its non-proliferation mandate, and the work of that advisory body is ongoing. So far, there is little published or publicly available information on the work of the Australia Group. However, to the extent that national security constraints might permit, it would be useful for ongoing consideration of the adequacy of international environmental law to be informed by the work and analysis of the Australia Group in relation to synthetic biology.

VII CONCLUSION

Synthetic biology clearly shows great promise for future developments in biotechnology. However, there are great risks too. There is an urgent need for closer examination of the implications of synthetic biology for international environmental law and in particular the *CBD* and the *Cartagena Protocol*. This article has outlined the emerging debates at the forums associated with the *CBD* and has highlighted numerous issues that need further examination by scholars and practitioners of international environmental law. The speed at which synthetic biology is transforming the biotechnology industry lends some urgency to the task at hand. While recent developments at the *CBD* are encouraging, like so many new frontiers of science in the past, law, and international environmental law in particular, is slow in coming to terms with the challenges of this revolutionary technology.

Developing new law or making old law fit for new challenges is never easy, but the potential risks of this technology in particular mandate an urgent assessment of the capacity of international environmental law to respond to the biosafety risks, risks to human health and the environment posed by synthetic biology. The potential opportunities this technology offers humanity should also be recognised and a reasonable balance be struck between the risks and the rewards of the synthetic biology revolution.

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[64] *BTW Convention*, art IV.

[65] James Martin Center for Non-Proliferation Studies, *Inventory of International Non-proliferation Organizations and Regimes* (10 May 2013) Monterey Institute of International Studies <http://cns.miis.edu/inventory>.