

# REPORT ON MACQUARIE UNIVERSITY WORKSHOP ON ETHICAL, LEGAL AND SOCIAL ISSUES RAISED BY SYNTHETIC BIOLOGY (10 DECEMBER 2014)

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## I INTRODUCTION

In mid-2014 Macquarie University, partnered by the Australian Wine Research Institute, announced its involvement in the Sc2.0 synthetic biology project.<sup>1</sup> The project, which follows the synthesis of the third chromosome found in yeast by Professor Jef Boeke of New York University,<sup>2</sup> aims to build the world's first completely synthetic yeast (*Saccharomyces cerevisiae* (*Sc*)) genome by engaging in a global partnership to synthesise the remaining 15 chromosomes by 2017. This task involves a partnership between scientists across the globe from New York University, John Hopkins University, the Joint Genome Institute, Beijing Genomics Institute, Tianjin University, Tsinghua University, Imperial College London, the University of Edinburgh and Macquarie University. In Australia, the research has been backed by \$1 million in funding from the NSW Office of the Chief Scientist and Engineer, and the NSW Department of Primary Industries. The Macquarie University Sc2.0 project is led by Professor Sakkie Pretorius,<sup>3</sup> whose team will work to design and synthesise yeast chromosomes 14 and 16.

The Sc2.0 project is clearly a project of the future, building upon Macquarie University's active involvement in research and teaching in this area for some years. For example, Macquarie's undergraduate students have competed in the International Genetically Engineered Machine (iGEM) competition for the past four years, being the top Australian team in each of these years, and winning two silver and two bronze medals internationally. Macquarie also has several projects in its Faculty of Science that in some shape or form are linked with, or on the path of, synthetic biology.<sup>4</sup>

However, the field of synthetic biology goes further in that it focuses upon building novel and/or artificial biological parts, organisms, devices and systems. Thus, as is often the case with emerging technologies, an increasing discourse about the ethical, legal, and social issues raised by such research, and its potential applications, has also been seen alongside the rise of this technology. What is striking about the *Sc2.0* project is that the members have embraced such discussion, wanting to ensure a multi-disciplinary and collaborative

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<sup>1</sup> Macquarie University, *Yeast 2.0 Project Launched* (2 June 2014)

<<http://mq.edu.au/thisweek/2014/06/02/yeast-2-0-synthetic-biology-project-launched/#.VSSYWuFlyXc>>.

<sup>2</sup> Narayana Annaluru et al, 'Total Synthesis of a Functional Designer Eukaryotic Chromosome' (2014)

344(6179) *Science* 55, 55–58; *The Economist*, *Synthetic Biology: DIY Chromosomes* (29 March 2014)

<<http://www.economist.com/news/science-and-technology/21599754-first-synthetic-chromosome-creature-complex-cells-designed>>.

<sup>3</sup> Professor Pretorius is the Deputy Vice Chancellor of Research at Macquarie University and a leading scientist in the field.

<sup>4</sup> For example, Macquarie scientists are working on the design of synthetic cyanobacteria for biofuels (Professor Ian Paulsen); integrin gene cassettes for design of expression modular proteins (Mike Gillings); design of self-assembling proteins as nanofabrication tools (Bridget Mabutt); development of nanodiamonds for biomolecular tags (Louise Brown); development of fungi and bacteria protein factories (Helena Nevalainen, Nicki Packer); and design and synthesis of light activated biological switches and devices (Rob Willows).

environment from the start. The workshop held at Macquarie University on 10 December 2014 therefore introduced, identified and discussed issues pertinent to the ethics and governance of synthetic biology research and potential future applications.<sup>5</sup> It engaged with current international research in relation to these issues, and identified how we may add to discourse at domestic and global levels.

This report provides an overview of the proceedings of the day; provides a short summary of what synthetic biology research and the Sc2.0 project is; outlines the possible benefits and potential risks of research and application that have been identified thus far in the synthetic biology field; and provides an introduction to various approaches to regulation and governance around the world. It also highlights views concerning what more may (or may not) be needed, as per the discussion at the workshop. Most of the remaining papers in this themed edition of the *Macquarie Law Journal* are written by a number of speakers from the event. The papers provide more detail about ethical, social, and/or legal and governance issues that were considered by speakers on the day. However, they are not merely reflections or summaries of what was spoken about, as a number have been further researched and subjected to double-blind peer review before being accepted for publication.

The articles and shorter papers published in this edition are intended to provide the basis for further discussion, thought and research concerning ethical, legal and social issues raised by synthetic biology and emerging technologies generally.<sup>6</sup> The report is not a wide and exhaustive review of the field of synthetic biology, but it reflects and elaborates on the discussions at the workshop. It is noted that the contents in this journal, like the workshop and ongoing work in the field, reflect the interdisciplinary approach being taken in this field. Such an approach is now seen as essential to any consideration of emerging technologies.

## II OVERVIEW OF PROCEEDINGS

The day long workshop took place on Wednesday 10 December 2014 at Trinity Chapel, Robert Menzies College in Sydney, Australia. The workshop was opened by Professor Mary O'Kane, the NSW Chief Scientist and Engineer, and was chaired by Professor Catriona Mackenzie, Fellow of the Australian Academy of the Humanities and an Executive Board Member of the Macquarie University Centre for Agency, Values and Ethics.

Distinguished speakers included:

- Professor Ian Paulsen, Professor of Genomics and Deputy Director of the Macquarie Biomolecular Frontiers Centre, Australian Laureate Fellow, Macquarie University. Professor Paulsen gave an overview of synthetic biology research, potential applications, and the Sc2.0 project.
- Dr Jane Calvert, Reader, Science Technology and Innovation Studies, School of Social and Political Science, University of Edinburgh. Dr Calvert delivered the keynote speech in which she discussed ideas, practices and promises of synthetic biology, drawing upon her interdisciplinary work in the sociology and anthropology of science, the philosophy of biology, and science policy.

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<sup>5</sup> The workshop was made possible via a \$12,000 grant awarded to Dr Sonia Allan and Professor Wendy Rogers by the Faculty of Arts, and administered through the Centre for Agency, Values and Ethics. Administrative and organisational support was provided by Swantje Lorrimer-Mohr and Jenna McClellan from MQ Campus Life.

<sup>6</sup> Note that the contents of this report are a summary of other works and information presented at the workshop, and are drawn from other researched materials. The report is an overview of proceedings on the day. Information is presented for education and discussion purposes and to highlight some matters of importance when considering the ethical, legal and social issues raised by synthetic biology.

- Debra J H Mathews, Assistant Director for Science Programs for the Johns Hopkins Berman Institute of Bioethics, secondary appointment in the Institute of Genetic Medicine, Assistant Professor in the Department of Pediatrics, Johns Hopkins School of Medicine. Dr Mathews presented via live video from the United States and discussed the self-regulatory governance framework developed for the Sc2.0 project.
- Dr Ainsley Newson, Senior Lecturer in Bioethics in the Centre for Values, Ethics and the Law in Medicine (VELiM) at the University of Sydney. Dr Newson presented on the ethics of synthetic biology, drawing on her longstanding interest and experience in the field, including a project grant from the European Commission in 2009 for the Synthetic Biology and Human Health Ethical and Legal Issues Project.
- Professor Wendy Rogers, Professor of Clinical Ethics in the Philosophy Department and the Australian School of Advanced Medicine at Macquarie University, Deputy Director of the Macquarie University Research Centre for Agency, Values and Ethics, and Australian Research Council Future Fellow.
- Dr Karolyn White, Director, Research Ethics and Integrity at Macquarie University and Associate Professor Subramanyam Vemulpad, Chair of Biosafety Committee, Deputy Associate Dean (HDR) for the Faculty of Science and Co-director of the Indigenous Bioresources Research Group and the National Indigenous Science Education Program. Dr White and Associate Professor Vemulpad spoke about responsible conduct of research.
- Dr Lisa Eckstein, Lecturer, University of Tasmania. Dr Eckstein discussed possible regulatory challenges for the future, such as whether synthetic biology should provide outcomes that lead to clinical trials in humans.

The author of this report, Dr Sonia Allan, presented a summary of the 'promises and perils' of synthetic biology, regulatory approaches taken around the world (and possible gaps), and responses to the technology from cautious support to calls for moratoriums. That information is included in the report below.

The workshop was presented to an audience that included students and representatives from universities across the country; representatives from the NSW Department of Health, the Office of Health and Medical Research, and the Department of Primary Industries; private organisations; and people from the industry and civil society (including, but not limited to, Gene Ethics and Friends of the Earth). There were also members from the general community and industry in attendance. Additionally, the Deputy Vice Chancellor of Research, Professor Sakki Pretorius, and the Pro-Vice Chancellor of Research, Integrity and Development, Professor Lesley Hughes, were present. There was lively discussion during question time and breaks, and at the end of the day, amongst attendees and with the speakers.

### III OVERVIEW OF SYNTHETIC BIOLOGY AND THE SC2.0 PROJECT

A number of speakers noted that there is no accepted agreement upon what 'synthetic biology' includes (or does not include), with its meaning continuing to be debated in academic circles. The Convention on Biological Diversity Subsidiary Body on Scientific, Technical, and Technological Advice notes:

'[A]reas of research that are commonly considered as 'synthetic biology' include DNA-based circuits, synthetic metabolic pathway engineering, genome-level engineering, protocell construction, and xenobiology. Some see the insertion of synthetically designed and produced DNA sequences or pathways into an existing genome largely as rebranding conventional biotechnology. Others consider the building of non-natural pathways that would be difficult to achieve with traditional genetic engineering and the

systematic engineering circuits and pathways as approaches novel to synthetic biology and distinct from traditional genetic engineering.<sup>7</sup>

However, there is general agreement that, as a scientific endeavor, synthetic biology aims to 'exercise control in the design, characterization and construction of biological parts, devices and systems'.<sup>8</sup>

Synthetic biology has further been explained as being a confluence of developments and breakthroughs in many disciplines including the biological sciences (genetics and genomics, molecular biology, systems biology), chemical sciences, mathematical sciences, computational sciences, data sciences, informatics, physical sciences, and engineering. With such advances in these fields combined it has become possible for molecular biologists to engage with the technology and explore possibilities of gene synthesis and replacement.<sup>9</sup> To date, the development of such research has taken place predominantly in the United States, China and the United Kingdom. Recently there has also been a growing number of research institutes working in the field in Europe.

The Sc2.0 project is representative of the large scale collaborative nature of synthetic biology research, which will require significant human resources to achieve its goals. That is, the work is intense and costly, and the involvement of multiple centres around the world is seen as a way of achieving what might otherwise not be possible.

Yeast has been chosen as a focus for the Sc2.0 project as it is a eukaryote, a single cell fungus which is considered a 'safe food-grade organism'.<sup>10</sup> It is easy to propagate, has well defined genetics, and is one of the most intensively studied biological model systems. It is seen as an 'industrial workhorse' as it is heavily involved in baking, brewing, winemaking, food production (such as Vegemite), biofuel production, and production of enzymes for pharmaceuticals, vaccines and other medicines.<sup>11</sup> Its potential for developing possible applications of synthetic biology is considered 'promising'.<sup>12</sup> However, while in some areas of research commercial or near-to-market products from, or related to, synthetic biology exist (for example, certain biofuels, organic chemicals, natural vanillin, synthetic biology produced squalene and semi-synthetic artemisinin), the Sc2.0 project is a first instance project that is not focused upon application. The research is aimed at developing the ability to synthesise the full 16 chromosomes contained in yeast. Macquarie University's task, as mentioned above, will be to synthesise chromosomes 14 and 16. Professor Paulsen noted that this is a very early stage project, and that significant applications may be a while off. However, that does not mean that there is not a lot of discussion about the potential promise

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<sup>7</sup> Convention on Biological Diversity Subsidiary Body on Scientific, Technical, and Technological Advice, *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*, 18<sup>th</sup> mtg, Agenda Item 6, UN Doc UNEP/CBD/SBSTTA/18/INF/3 (20 May 2014) 4.

<sup>8</sup> Ibid.

<sup>9</sup> Sakki Pretorius, *News Briefing: Man-made Life – Announcing Australia's Role in DIY DNA* (23 May 2014) Australian Science Media Centre <<http://www.smc.org.au/briefing-man-made-life-announcing-australias-role-in-diy-dna/>>.

<sup>10</sup> In the United States the classification of *Saccharomyces cerevisiae* by the Food and Drug Administration authority is that of 'GRAS' (generally recognized as safe); in Europe it is classified as 'QPS' (qualified presumption of safety). See, eg, US Environmental Protection Agency, *Saccharomyces Cerevisiae Final Risk Assessment* (February 1997) Biotechnology Program under the Toxic Substances Control Act <[http://www.epa.gov/biotech\\_rule/pubs/fra/fra002.htm](http://www.epa.gov/biotech_rule/pubs/fra/fra002.htm)>; R Leuschner et al, 'Qualified Presumption of Safety (QPS): A Generic Risk Assessment Approach for Biological Agents Notified to the European Food Safety Authority (EFSA)' (2010) 21 *Trends in Food Science and Technology* 425, 430–431.

<sup>11</sup> Sakki Pretorius, above n 9.

<sup>12</sup> Ibid.

such research holds. For example, in quoting the UK Science Minister, Professor Sakki Pretorius has noted that 'it is a technology that promises to heal us, feed us, fuel us, and to power our economy, improve our wellbeing, and protect our environment'.<sup>13</sup>

Alongside such discussion are concerns about synthetic biology, and a consciousness that, along with potential benefits, lies the potential for harm. It has therefore been recognised that an approach that ensures research and technology only moves in a direction beneficial to society is crucial to research and potential future applications.

#### IV THE PROMISES AND POTENTIAL PERILS OF SYNTHETIC BIOLOGY

A theme that was discussed by all speakers at the workshop was that it is important to recognise both the wide and varied intended benefits of synthetic biology as well as the potential risks to biological diversity and human livelihoods associated with the components, organisms and products resulting from synthetic biology techniques. It was noted that both benefits and concerns are well documented in synthetic biology literature,<sup>14</sup> as is the fact that some aspects of synthetic biology may raise dual use issues (ie may have the potential for use for good and for harm).<sup>15</sup> A recent comprehensive survey conducted by the Convention on Biological Diversity Subsidiary Body on Scientific, Technical, and Technological Advice, was used as a basis for discussion at the workshop in order to outline some of the key areas and issues that display the potential for both benefits and risks.<sup>16</sup> The following key areas and issues were noted and discussed.

##### *Bioenergy Applications*

Potential benefits: reduce global dependence on fossil fuels; cut harmful emissions; next generation biofuels; biomass as feedstock.

Potential risks: decrease soil fertility; displacement of local sustainable uses; environmental harm; encroachment on traditional uses; biosafety concerns (for example, accidental release of organisms).

##### *Environmental Applications*

Potential benefits: more effective and 'green' pollution control and remediation; biosensors to identify contamination.

Potential risks: biosafety considerations regarding deliberate release of micro-organisms.

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<sup>13</sup> Ibid.

<sup>14</sup> See, eg, Brian Rappert and Michael J Selgelid, *On the Dual Uses of Science and Ethics* (Australian National University Press, 2013); Hans-Jürgen Link, 'Playing God and the Intrinsic Value of Life: Moral Problems for Synthetic Biology?' (2013) 19 *Science and Engineering Ethics* 435; Presidential Commission for the Study of Bioethical Issues, 'New Directions: The Ethics of Synthetic Biology and Emerging Technologies' (Research Report, December 2010); Andrew Balmer and Paul Martin, 'Synthetic Biology: Social and Ethical Challenges' (Independent Paper, Institute for Science and Society, University of Nottingham, 2008).

<sup>15</sup> For a comprehensive coverage of the dual uses of science, see Rappert and Selgelid, above n 14, 45.

<sup>16</sup> Convention on Biological Diversity Subsidiary Body on Scientific, Technical, and Technological Advice, *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*, 18<sup>th</sup> mtg, Agenda Item 6, UN Doc UNEP/CBD/SBSTTA/18/INF/3 (20 May 2014).

### *Wildlife-targeted Applications*

Potential benefits: identify and treat wildlife diseases; restore extinct species; new paradigms for biodiversity advocacy; target threats such as disease vectors.

Potential risks: diversion of funds and resources from conservation efforts; move policy makers away from addressing underlying causes for biodiversity loss; moral hazard — decrease will to conserve endangered species.

### *Agricultural Applications*

Potential benefits: sustainable intensification; land sparing; reduce chemical pesticides and fertilizers; drive land use.

Potential risks: biosafety considerations regarding the deliberate release of SynBio organisms.

### *Replacing Natural Materials*

Potential benefits: plant and animal conservation currently unsustainably harvested from the wild or through unsustainable cultivation.

Potential risks: displacement of products key to in-situ conservation; biosafety considerations around accidental release of micro-organisms.

### *Replacing Materials Made with Synthetic Chemistry*

Potential benefits: decreased use of non-renewable resources and less environmentally harmful manufacturing processes; sustainable production and consumption (which also protects biodiversity).

Potential risks: may not actually be greener (for example, bioplastics); drive significant land use changes towards feedstock production; biosafety considerations regarding accidental release of micro-organisms.

### *Biosecurity*

Potential benefits: better identification of pathogenic agents; response to biosecurity threats (for example, accelerated vaccines).

Potential risks: dual use challenge (for example, creating destructive pathogens).

### *Economic Applications*

Potential benefits: bioeconomy; economic growth, human health and environment; products such as artemisinin may improve human health in developed countries and therefore their economies.

Potential risks: product displacement harming economies; displacement of livelihoods of small-scale farmers and pickers; extraction and use of biomass may be ecologically unsustainable.

### *Health Applications*

Potential benefits: study of disease mechanisms; aid in diagnostics; drug discovery; drug screening; organisms that produce drugs and vaccines; therapeutic treatments.

Potential risks: possibility of direct harm to patients' health if engineered organisms/viruses trigger unanticipated adverse events; direct harm to workers in labs; patents restrict access to drugs and therapies.

### *Open Intellectual Property*

Potential benefits: innovation, transparency and openness; avoidance of patenting issues that relate to natural DNA.

Potential risks: may extend private ownership of genetic material, restricting public access; restricts access to information for carrying out independent risk assessments.

In addition, two further significant concerns were noted at the workshop: whether the transfer of genetic material from an organism resulting from synthetic biology techniques to another organism would change biodiversity at a genetic level and spread undesirable traits; and whether synthetic biology could result in radically different forms of life, with 'unpredictable and emergent properties'.

The following statement by Dana et al was therefore also considered:

'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.'<sup>17</sup>

The statement highlights that there are also 'unknown unknowns' that need to be identified, considered, and addressed.

However, there are also considerations to be had about the benefits of such research. The following statement was also considered:

'It is easy (and perhaps appropriate) for an enumeration of the potential risks of synthetic biology to sound alarming. But these must be weighed against the benefits, not least in the sense that there is an ethical component to the decision to forego a new technology too: there can be socially significant penalties to the seemingly 'safe' option of 'doing nothing.' For one thing, the powerful capabilities synthetic biology might provide for developing and manufacturing drugs, including ones sorely needed in developing countries, should not lightly be set aside, just as we do not prohibit all drugs that have side-effects. It is conceivable that in the long-term, synthetic biology might offer one of the most powerful approaches for ameliorating natural biological and ecological hazards such as the spread of infectious diseases.'<sup>18</sup>

It was highlighted in the workshop that the tensions between promises and potential perils were great, and further ethical issues were highlighted and discussed. These tensions raise questions rather than give answers. What level of governance and regulation is needed? How do we allow the science to move forward while not ignoring risks? What level of risk are we as a society willing to accept? Should a precautionary approach be preferred? This led into the next part of the discussion concerning governance and regulation.

## V DIFFERING VIEWS REGARDING GOVERNANCE/REGULATORY APPROACHES THAT SHOULD BE TAKEN TO ADDRESS THE PROMISES AND PERILS OF SYNTHETIC BIOLOGY

Two differing views regarding how to address the promises and perils of synthetic biology by way of governance/regulatory options were highlighted (and discussed) at the workshop. These were a soft law approach, which would enable research to move forward under

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<sup>17</sup> Dana Genya et al, 'Four Steps to Avoid a Synthetic Biology Disaster' (2012) 483(7387) *Nature* 29.

<sup>18</sup> Mukunda et al, 'Guidelines for the Appropriate Risk Governance of Synthetic Biology' (Policy Brief, International Risk Governance Council, 2010).

guidelines, codes of practice and ethical undertakings by researchers, as contrasted with a complete moratorium on, at the very least, the release and commercial use of synthetic biology. The latter may prohibit or prevent certain types of research and it generally calls for the prevention of all release or commercialisation of research products or outcomes. The two approaches are further discussed below.

#### A *Soft Law (and Self-Regulation) as a Governance Option*

Attendees at the Macquarie University workshop were asked to consider the following statement made by Mandel and Marchant concerning the atypical characteristics of synthetic biology, and their suggestion to fill gaps with soft law options:

'The rapidly emerging technology of synthetic biology will place great strain upon the extant regulatory system due to three atypical characteristics of this nascent technology:

- synthetic biology organisms can evolve;
- traditional risk structures do not apply; and
- the conventional regulatory focus on end-products may be a poor match for novel organisms that produce products ...

[However] due to the uncertainty present at this early stage of synthetic biology development, and the practical political context, it is unlikely that the significant statutory and regulatory gaps identified could be cured directly. ... [A] selection of soft law alternatives ... could more quickly provide flexible and adaptive measures to help fill regulatory gaps in a manner that allows this promising technology to develop as rapidly as possible, while still adequately guarding against risks to human health and the environment.'<sup>19</sup>

The significance of the statement was discussed in relation to the three atypical characteristics that Mandel and Marchant highlight. Particular focus was had upon the challenges faced in using strict laws to regulate rapidly changing technologies.

It was noted that in referring to soft law options, Mandel and Marchant refer to such things as voluntary programs, consensus standards, partnership programs, codes of conduct, principles and certification programs. They note that 'such tools can impose substantive expectations or requirements, but unlike traditional hard law government regulations, are not directly enforceable'.<sup>20</sup>

The workshop highlighted that the soft law approach is very much the approach taken in the United States (the lead centre for the Sc2.0 project) for the regulation and governance of synthetic biology. Much governance of synthetic biology takes place there via the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, which, along with the Recombinant DNA Advisory Committee (RAC), have governed DNA research for decades in the United States. The guidelines are used to determine risk and biosafety levels of organisms used in research, to ensure proper handling and containment, and to minimise risk stemming from use.

In addition, the United States Department of Health and Human Services (DHHS) has issued a set of voluntary guidelines for companies producing and selling DNA to ensure that a DNA sequence ordered for synthesis does not code for harmful agents or toxins. The guidelines also provide for and validate the identity and credibility of the individual ordering

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<sup>19</sup> Gregory N Mandel and Gary E Marchant, 'The Living Regulatory Challenges of Synthetic Biology' (2014) 100 *Iowa Law Review* 155.

<sup>20</sup> *Ibid.*



the DNA. If a company has concerns and cannot resolve them, the company is advised to contact the FBI Office of Weapons of Mass Destruction.

The International Risk Governance Council (IRGC) has also published a set of guidelines which address biosafety and biosecurity; engagement of the public and other stakeholders; and ongoing, interdisciplinary dialogue to inform policy. The IRGC guidelines call for an internationally uniform method for DNA synthesis companies to screen requests; the conduct of regular audits to ensure that labs are following the appropriate safety precautions; and continued development of built-in safeguards that can mitigate risks in the event of accidental release.

Dr Debra Mathews, a member of the Sc2.0 project, also spoke about a specific statement of ethics and governance, which is the self-regulatory agreement made by all participants in the project.

### *1 The Sc.2.0 Project Statement of Ethics and Governance*

Dr Matthews gave an overview of the Sc2.0 project before discussing the history of governance in the field. She highlighted that synthetic biology research falls upon a continuum of recombinant DNA research (rDNA) and that, as such, it has a long history of self-governance. In the early 70s, scientists made a decision to look at self-governance to prevent risks in relation to rDNA. This took place starting with the 'Asilomar Conference' and moved to the above noted NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and RAC. Dr Mathews noted that the remit of the current guidelines and RAC have developed and are quite different to their original form.

Moving to discuss synthetic biology specifically, Dr Mathews said that in the United States there is not a lot of 'formal governance', so the abovementioned NIH and DHHS guidelines are important. Nevertheless, in relation to the Sc2.0 project, she noted that early consideration was given to the issue of having a further unifying document that articulates the major policy and ethical issues related to the project, and the collective approach to be taken in relation to these issues. This document is important due to the global nature of the project that relies upon over 300 scientists from different backgrounds, working in diverse settings together. After much discussion and consultation, the result was a Sc2.0 ethics and governance document which was finalised and circulated to all project scientists in 2013. The document is incorporated in all new agreements that each participating site must sign prior to joining the project, and is added as an amendment to all previously executed partnership agreements. The document was circulated at the workshop.

Dr Mathews described the document as containing 11 statements to which all Sc2.0 participants agree to adhere. She further described the statements as falling into four main categories, being societal benefit, safety, intellectual property, and governance. The following is a summary of the Statement of Ethics and Governance set out pursuant to those four categories.

#### *(a) Societal Benefit*

##### *(i) Statement 1: Do No Harm*

The first statement in the ethics and governance document is as follows:

'As scientists and humans participating in the Sc2.0 Project, we wish for our work to contribute to the benefit of society and not to bring harm. The work on Sc2.0 will be

done only in service to peaceful purposes. Further, individual participants and the Sc2.0 Executive Committee will make efforts to ensure that all the benefits from Sc2.0 are maximized and any potential harms of Sc2.0 are minimised.'

The statement is of course aspirational and cannot guarantee that all people will work as described, but nevertheless requires that anyone working on the Sc2.0 project undertakes to act in this manner.

*(ii) Statement 2: Transparency and Public Engagement*

The second statement requires a commitment to 'transparency and public engagement'. It notes that the Boeke lab maintains an Sc2.0 website,<sup>21</sup> which is viewed as their 'public engagement venue with the broadest reach'. It states that project participants will 'contribute information to the resource in a timely fashion'. It is assumed that such information would include, for example, information about the science, ethics, governance and funding of the project — although this is not explicit. Information on such matters can also be found on various websites around the world describing respective participants' involvement and funding.<sup>22</sup> Statement 2 also refers to the Boeke lab being primarily responsible for public outreach. In addition, 'all Sc2.0 participants are encouraged to hold public lectures' (and will be supported via powerpoint slides and handouts from the Boeke lab).

The statement notes that the public are directly involved in the project, through partnerships with the LA Biohackers (a group of amateur scientists with a lab based in Downtown LA who provide space and equipment for people to work on their own biology projects and experiments)<sup>23</sup> and students at New York City's private Dalton High School, and that 'outreach will continue throughout the duration of the project'. Finally, it states that all Sc2.0 project participants are 'encouraged to make efforts to publicize both the potential and actual benefits *and* potential risks of Sc2.0 and other synthetic biology projects, in a way that lay people can understand'.

*(b) Safety*

*(i) Statements 3 to 6: Safety Concerns*

Statement 3 supports the use of the DHHS 'Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA' and requires that all sequence providers generating DNA for use in the Sc2.0 project are compliant with those guidelines.

Statement 4 requires that members of the Sc2.0 team access individuals requesting Sc2.0 project data/materials prior to shipment of such data/materials to 'help reduce the chance ... [of members] distributing materials to those with nefarious intent'.

Statement 5 is that the Sc2.0 project embraces and employs rigorous safety practices. It notes that there are no plans to intentionally release the completed synthesized yeast (or any components or intermediaries) into the environment. Nevertheless, all strains are to contain a number of 'auxotrophic mutations' which are intended to render them unlikely to be able

<sup>21</sup> Boeke Lab, *Home* (9 January 2015) Synthetic Yeast 2.0 <<http://syntheticyeast.org/>>.

<sup>22</sup> See, eg, Research Councils UK, *The Sc2.0 UK Genome Engineering Resource (SUGER)* (26 March 2015) Gateway to Research <<http://gtr.rcuk.ac.uk/project/E7645B9A-1C1D-47A4-82ED-6E3D606525C9>>; Macquarie University, *Yeast 2.0 Project Launched* (2 June 2014) <<http://mq.edu.au/thisweek/2014/06/02/yeast-2-0-synthetic-biology-project-launched/#.VSWfAuGEPT9>>.

<sup>23</sup> Los Angeles Biohackers, *Home* (7 February 2015) <<http://www.biohackers.la/>>.

to survive long-term outside of the laboratory. Research is required to further ensure that this process is appropriate and ongoing.

Statement 6 addresses safety concerns by providing that all faculty and staff will receive training on biosafety, dual-use concerns, and other ethics issues as appropriate. Dr Mathews explained that such training included lectures, the use of the National Science Advisory Board for Biosecurity's (NSABB) educational module for individual learning, and group discussion. Additionally, the group has been developing an online course on the ethics and policy issues related to synthetic biology that will be freely-available to all.

*(c) Intellectual Property*

*(i) Statements 8 and 9: Open Source Attitude*

Statement 8 notes the Sc2.0 project members' 'commitment to facilitating innovation and maximizing the beneficial use of Sc2.0'. Members of the Project agree that no intellectual property rights or restrictions on data and materials sharing should be exercised on the clones used to generate novel strains, intermediary strains, or the final Sc2.0 strain.

Statement 9 provides that data and materials of the Sc2.0 project will be made available to other scientists. All primary products of the Sc2.0 project, including the clones used to create novel strains, intermediary strains, or the final Sc2.0 strain will be made available at a cost to the broader community through a central repository.

*(d) Governance*

*(i) Statements 7, 10 and 11: Governance Structure*

Statement 7 provides that all work on the Sc2.0 project will comply with any relevant laws and policies.

Statement 10 provides that oversight of safety and compliance with the statement is the responsibility of the Sc2.0 project Executive Committee — a committee that consists of individuals with scientific, ethics and policy expertise. Safety or compliance issues or concerns may be brought to the attention of that committee by anyone. The Committee has the authority to remove from the Sc2.0 project any partner that violates the Statement of Ethics and Governance.

The final statement provides that '[u]nderstanding that science advances very quickly and that local and national policies may also change over time, the Executive Committee will regularly review the Statement to ensure that the project policies appropriately reflect the risks and regulatory status of the project. If the risks increase, so will oversight and accountability'.

It was noted by Dr Mathews that while project-level accountability will not suffice to regulate all of synthetic biology, the Sc2.0 Statement of Ethics and Governance provides a valuable model for component self-regulation in the field. It may serve to fill the gaps in current oversight mechanisms via voluntary self-regulation, and aims to support work being conducted in a scientifically justifiable and ethically sound way.

*B Moratorium on the Release and Commercial Use of Synthetic Biology until Robust Regulation and Rigorous Biosafety Measures are Established*

The second approach to governance that was discussed at the workshop was the call for a world-wide moratorium on the release and commercial use of synthetic organisms until more robust regulations and rigorous biosafety measures are established. Such a call was issued on 13 March 2012 by over 100 environmental and civil society groups.<sup>24</sup> The following Executive Summary of that document was displayed for discussion:

Synthetic biology, an extreme form of genetic engineering, is developing rapidly with little oversight or regulation despite carrying vast uncertainty. Standard forms of risk assessment and cost-benefit analyses relied on by current biotechnology regulatory approaches are inadequate to guarantee protection of the public and the environment.

The Precautionary Principle is fundamental in protecting the public and our planet from the risks of synthetic biology and its products. A precautionary approach requires synthetic biology-specific oversight mechanisms that account for the unique characteristics of synthetic organisms and their products. Additionally, it assesses the novel consequences of synthetic organisms and products of synthetic biology as well as full consideration of alternative options.

Ensuring public health, worker safety and ecosystem resilience requires a committed focus on developing a critical public interest research agenda that includes risk research and development of alternatives, a robust pre-market regulatory regime, strong enforcement mechanisms, immediate action to prevent potential exposures until safety is demonstrated and ongoing monitoring for unintended consequences and immediate action to prevent potential exposures until safety is demonstrated.

Protection of the public includes a ban on using synthetic biology to manipulate the human genome in any form, including the human microbiome. Decisive action must also be taken to protect the environment and human health and to avoid contributing to social and economic injustice. Developers and manufacturers must be responsible for the safety and effectiveness of their processes and products and must retain liability for any adverse impacts.

Throughout, research and regulation shall be transparent and provide public access to all information regarding decision-making processes, safety testing and products.

Open, meaningful and full public participation at every level is essential and should include consideration of synthetic biology's wide-ranging effects, including ethical, social and economic results.

No synthetic organism or their synthetic building blocks should be commercialized or released without full disclosure to the public of the nature of the synthetic organism and results of safety testing.

This document outlines the following principles necessary for the effective assessment and oversight of the emerging field of synthetic biology:

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<sup>24</sup> Friends of the Earth, International Center for Technology Assessment and ETC Group, 'The Principles for the Oversight of Synthetic Biology' (Declaratory Report, 13 March 2012).

- |      |   |
|------|---|
| I.   | Employment of the Precautionary Principle             |
| II.  | Mandatory synthetic biology-specific regulations      |
| III. | Protection of public health and worker safety         |
| IV.  | Protection of the environment                         |
| V.   | Guaranteed right-to-know and democratic participation |
| VI.  | Corporate accountability and manufacturer             |
| VII. | Protection of economic and environmental justice.     |

It was noted that the manifesto called for:

‘[G]overnmental bodies, international organizations and relevant parties to immediately implement strong precautionary and comprehensive oversight mechanisms enacting, incorporating and internalizing [the above] principles. Until that time, there must be a moratorium on the release and commercial use of synthetic organisms and their products to prevent direct or indirect harm to people and the environment.’

It was further noted at the recent United Nations Conference of the Parties to the Convention of Biodiversity in October 2014 that:

- many countries have stressed the need to apply the precautionary approach to synthetic biology;
- there has been a call to set up systems to regulate the environmental release of any synthetic biology organisms or products; and
- there has been great emphasis on risk assessment to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations.

It was proposed by some countries (Malaysia and the Philippines) that a global international legal regulatory framework should be developed. The call was supported by a number of African countries, including Cameroon, Kenya, Liberia and South Africa. In Latin America, Bolivia and the Dominican Republic also supported a precautionary approach. Yet other countries opposed such suggestions including Australia, Canada, New Zealand the UK and the European Commission.

In addition to a call for a moratorium, some nations called for there to be discussion of whether it is necessary:

- to license and regulate the limited number of firms that provide raw materials for DNA synthesis;
- to regulate DNA synthesis machinery; and
- to expand the Nagoya Protocol (discussed below) to cover digital genetic sequences.

It was noted that the call for a moratorium is not arguing for the prevention of all research. Rather, it is based on the view that there are significant risks that have not yet been properly assessed and/or lack robust regulation, and that soft law options may fill the gap in some areas but are not enough to prevent serious impacts upon human health, biodiversity, food security, and the economy of some nations.

## C Discussion

Reflecting upon the above information, as well as the presentations given by other speakers at the workshop who discussed ethical issues raised by synthetic biology research, both the positives and negatives of soft law governance options, and/or the proposed moratorium, were noted.

Soft law options are particularly useful in areas of emerging technology that are developing at a rapid pace, such as synthetic biology. They enable decisions to be revisited and amended in response to new information on risks and potential benefits. They can also include measures and actions that provide a broader approach to governance. For example, the education of potential users of synthetic DNA can inform them about ethical practices, risks, and consequences; the compilation of a manual for biosafety in synthetic biology laboratories might provide more immediate information and guide practices within the laboratory; and broad roles for Institutional Biosafety Committees to identify and review experiments for both safety and security concerns may enhance the enforcement of, and compliance with, biosafety guidelines. Mandel and Marchant also note that soft law measures can be extended beyond national and regional boundaries, are collaborative rather than adversarial, and promote a 'moral sense of ownership within a professional culture of responsibility'.<sup>25</sup>

However, Mandel and Marchant also emphasise that such measures may not provide the normal procedural safeguards that are an important part of traditional regulation, and may serve to reduce transparency or exclude relevant stakeholders from the decision-making process.<sup>26</sup> In addition, there is some evidence that voluntary soft law programs are less effective than traditional regulation in 'providing consumer confidence that a technology or industry is being kept in check by government regulation, and providing certainty to companies and investors about regulatory requirements'.<sup>27</sup> Although soft law options play an important role in the governance of emerging technologies, they are not generally seen as an answer to *all* issues raised by such technologies.

At the workshop there was no opposition shown to using soft law options as part of an approach to the governance of synthetic biology. However, the extent to which they were adequate was the subject of some disagreement. The discussion regarding whether a moratorium was required provided for strong reactions from audience members who both supported and rejected the notion. Some were of the view that synthetic biology is no different to other forms of emerging technology; some were wholly supportive of the research and saw a cautious but progressive approach as necessary; others were adamant that the science is moving too fast, and poses unacceptable (and perhaps catastrophic) risks to humankind and/or the environment. Others still noted that differentiation within the field concerning what is good and what may be harmful also needs to occur. For example, Newson notes that it is obviously important not to leave populations or environments worse off in any way as a result of synthetic biology, but 'not everything that is produced in synthetic

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<sup>25</sup> Presidential Commission for the Study of Bioethical Issues, above n 14, 36–50.

<sup>26</sup> Mandel and Marchant, above n 19.

<sup>27</sup> *Ibid.* Mandel and Marchant point to a number of studies showing that the public has less confidence in voluntary programs providing adequate oversight. See, eg, Elenore Pauwels, 'Public Understanding of Synthetic Biology' (2013) 63 *BioScience* 79, 86 (52% of public thought government should oversee synthetic biology, while 36% believed voluntary guidelines developed jointly by government and industry would provide adequate oversight); Jennifer Kuzma, Pouya Najmaie and Joel Larson, 'Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms' (2009) 37 *Journal of Law, Medicine and Ethics* 546.

biology research will have biosafety [or other negative] implications' and some products may be benign or not capable of infection.<sup>28</sup>

It was noted by a number of speakers and audience members at the workshop that the history of recombinant DNA research has always included discussion and fears of new kinds of diseases, altering human evolution or irreversibly altering the environment, and similar arguments about what to do in relation to perceived risks. For example, in its earliest stages, the ability to clone DNA segments resulted in a voluntary moratorium on certain rDNA experiments in mid-1974 due to concerns that the unfettered pursuit of the research might result in unforeseen and damaging consequences for human health and the earth's ecosystems.<sup>29</sup> The moratorium was universally observed, providing time for a conference to evaluate the state of the new technology and any risks associated with it. The conference, held at the Asilomar Conference Center in California, United States (which would famously go on to be referred to as 'the Asilomar Conference'), included scientists from around the world, lawyers, government officials and members of the press. One outcome of the conference was the decision to proceed with research under strict guidelines, which were subsequently promulgated by the National Institutes of Health and by other comparable bodies around the world. Despite opposition to this decision, the research has persisted.

Regulatory approaches have continued to differ around the world. For example, some nations enacted legislation that prohibits or restricts genetically modified plants and animals from entering their food supply. However, it was noted that no such embargo had been placed upon certain drugs and therapies currently used in the treatment of serious diseases that were created with the same technology.

It is clear that there are large ongoing questions and different points of views from people all over the world. It is also important to recognise that the issues discussed at the workshop are ones with a long history that has occurred along a continuum of scientific research and development. Therefore, it is also important to consider what regulation and governance currently exists, while also considering what more (if anything) is needed.

## VI CURRENT REGULATION OF SYNTHETIC BIOLOGY AROUND THE WORLD

Current regulation relevant to synthetic biology was therefore discussed at the workshop, although comprehensive discussion was not possible due to limited time. It was noted that there are some existing national and international regulatory regimes that serve to regulate the components, organisms and/or products resulting from synthetic biology to some degree, but they do not form a coherent and comprehensive international framework. There are gaps at both international and domestic levels.<sup>30</sup>

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<sup>28</sup> Ainsley Newson, 'Synthetic Biology: Ethics, Exceptionalism and Expectations' (2015) 15 *Macquarie Law Journal* 45.

<sup>29</sup> Paul Berg, *Asilomar and Recombinant DNA* (26 August 2004) Nobel Prize <[http://www.nobelprize.org/nobel\\_prizes/chemistry/laureates/1980/berg-article.html](http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1980/berg-article.html)>.

<sup>30</sup> Note that the information included in the overview of regulatory approaches was extracted from a number of documents that have considered these issues in more detail, and was used for education and discussion purposes. For detailed discussion of these issues, see, eg, Mukunda et al, above n 18; Margo A Bagley and Arti K Rai, 'The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts' (Research Report, Woodrow Wilson International Center for Scholars, November 2013); Committee on Science, Technology and Law et al, *Positioning Synthetic Biology to Meet the Challenges of the 21st Century: Summary Report of a Six Academies Symposium Series* (National Academies Press, 2013); Shlomiya Bar-Yam et al, 'The Regulation Of Synthetic Biology: A Guide to United States and European Union Regulations, Rules and Guidelines' (Discussion Paper, NSF Synthetic Biology Engineering Research Center, 10 January 2012).

## A *International Regulation, Governance and Oversight*

At an international law level several protocols, conventions and agreements were noted.

### 1 *The Cartagena Protocol on Biosafety for Living Modified Organisms*

The Cartagena Protocol on Biosafety for Living Modified Organisms (LMOs) to the Convention on Biological Diversity regulates international trade in LMOs and establishes an advanced informed agreement procedure, based on risk assessment, regarding acceptance/rejection decisions of LMOs by countries to which they are being shipped. The Protocol also allows the recipient nation to invoke precautionary regulation if, in its judgment, there is not enough scientific information to make a proper assessment of the potential adverse effects of the LMO on the conservation and sustainable use of biodiversity or risks to human health. There are 157 parties to the agreement.

There are a number of outstanding issues relating to the oversight of genetic manipulation technologies even after adoption of the Protocol text. These include:

- LMOs is a more restricted category than genetically modified organisms (GMOs), since it excludes those that are no longer alive, and their products;
- 'intentional introduction into the environment' may not address situations where the exporter knows that some shipped modified grain, for instance, will be planted within the importing country, but does not necessarily intend this to happen;
- many important countries are not members of the Protocol, including the largest growers and exporters of LMOs: the United States, Canada, Argentina and Australia;
- the Protocol's provisions on trade in LMOs between a party and a non-party state does not require that its procedures be followed; and
- the Protocol says nothing about any regulatory oversight within a country.

Developments in synthetic biology could also lead to gaps in the risk assessment framework set out in the Cartagena Protocol, since established practices may not be capable of dealing with complex hybrids of genetic material (including some that are wholly synthetic in design and origin) and the properties and effects they display.

It was noted that on 14 October 2014, the United Nations Conference of the Parties to the Convention on Biological Diversity urged all member countries to:

- follow a precautionary approach to synthetic biology;
- 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 on Biological Diversity. These regulations must ensure that activities in one country cannot harm the environment of another;
- 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;
- 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. These assessments should take into account risks to human health and address other issues such as food security and socioeconomic considerations with the full participation of indigenous and local communities according to national and/or regional legislation;



- encourage the provision of funding for research into synthetic biology risk assessment methodologies and 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; and
- cooperate in the development and/or strengthening of human resources and institutional capacities, including methodologies for risk assessments, in synthetic biology and its potential impacts on biodiversity in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement.<sup>31</sup>

The committee noted that ‘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’.<sup>32</sup>

The decision also:

- establishes an ongoing process within the Convention on Biological Diversity, including an expert group which will establish a definition of synthetic biology and identify whether existing governance arrangements are adequate; and
- invites other UN bodies to consider the issue of synthetic biology as it relates to their mandates.<sup>33</sup>

## 2 *The Nagoya Protocol to the Convention on Biological Diversity*

The Nagoya Protocol to the Convention on Biological Diversity<sup>34</sup> may also be relevant to synthetic biology. It has the stated purpose of ensuring ‘fair and equitable sharing of benefits arising out of the utilization of genetic resources’, which covers all organisms. The Protocol requires researchers to enter into ‘access and benefit sharing’ (ABS) arrangements concerning organisms being used. An ABS sets out who might profit, and how, from the organisms being used. It also stipulates how to distribute the benefits fairly, such as co-authorship of publications or sharing profits from products such as drugs, vaccines or crops.

A number of issues have been raised in relation to the Nagoya Protocol and synthetic biology. First is the issue of whether it applies to synthetic biology at all, and if so, to what extent. A 2013 report written for the Woodrow Wilson Foundation found significant uncertainty surrounding what sorts of genetic materials are covered.<sup>35</sup> The report noted three questions left unanswered: Would synthetic DNA or BioBricks be covered? Would genetic samples collected prior to the ratification of the treaty be covered? Would digital DNA sequences shared over the web be covered? Nevertheless, the report suggested that, at a minimum, researchers must verify the origin of the genetic material they use and ensure

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<sup>31</sup> See Conference of the Parties to the Convention on Biological Diversity, *New and Emerging Issues: Synthetic Biology*, 12<sup>th</sup> mtg, Agenda Item 24, UN Doc UNEP/CBD/COP/12/L.24 (17 October 2014).

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.

<sup>34</sup> The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. In accordance with its Article 32, the Protocol was opened for signature from 2 February 2011 to 1 February 2012 at the United Nations Headquarters in New York by Parties to the Convention. The Protocol entered into force on 12 October 2014. To date, it has 57 Parties, 59 ratifications and 91 signatures.

<sup>35</sup> Margo A Bagley and Arti K Rai, above n 30.

such material is taken in compliance with the domestic law of a provider country – regardless of whether they are signatories to the Nagoya Protocol.

Second, it has been suggested that the Nagoya Protocol rules will present challenges for synthetic biologists who combine genetic code from many different organisms to create drugs or sensors. In particular, if they do apply, there is a question of whether such practices could require dozens of ABS arrangements for a single product. Of note is that one CEO of a synthetic biology company suggested that, if this were the case, companies would simply move to a nation (such as the United States) that is not a party to the Protocol to avoid such ‘bureaucracy’.

### 3 *The Biological Weapons Convention*

The Biological Weapons Convention (which opened for signature in 1972 and entered into force in 1975) prohibits the development, production, acquisition, transfer, retention, stockpiling and use of biological and toxin weapons. It is a key element in the international community’s efforts to address the proliferation of weapons of mass destruction. This includes:

- microbial or other biological agents, or toxins that have no justification for prophylactic, protective or other peaceful purposes; and
- weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

However, there is a challenge regarding the monitoring of compliance. Ambassador Masood Khan, President of the Sixth Review Conference of the Biological Weapons Convention and Chairman of its meetings in August 2007 said:

‘[E]xtraordinary advances achieved in biosciences meant that biological weapons were – in theory – within reach of the smallest laboratory and most modest budget. No government, no international organization, could hope to monitor effectively the tens of thousands of small biotechnology facilities in operation worldwide. Clearly, this was a problem that needed a collective, multifaceted and multidimensional approach.’<sup>36</sup>

Ambassador Khan notes that in order to even begin to address this there needs to be a network of collaboration and coordination ‘that must weave international, regional and domestic strands into a flexible and resilient fabric of oversight and prevention’.<sup>37</sup>

The Australia Group was also noted as being relevant to considerations about the possibility of chemical or biological weapon development. The Australia Group is an informal association of 41 member states that aims to allow exporters or transshipment countries to minimise the risk of proliferation of chemical and biological weapons (CBW). It aims to limit the spread of CBW through the control of chemical precursors, CBW equipment, and biological weapon agents and organisms. All participating countries have licensing measures covering over 60 chemical weapon precursors.<sup>38</sup>

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<sup>36</sup> Masood Khan, ‘Strengthening a Global Biosecurity/Biosafety Framework and Coping with the Biotechnology Revolution’ (Speech delivered at the Biological Weapons Committee Meeting, Como, 25–26 October 2007).

<sup>37</sup> *Ibid.*

<sup>38</sup> See also The Australia Group, *Home* (2007) <<http://www.australiagroup.net/en/index.html>>.

#### 4 *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most comprehensive multilateral agreement on intellectual property, setting standards to be met in domestic patent law. Most applications and techniques of synthetic biology would be patentable under Article 27.3(b) of the Agreement, which deals with intellectual property protection of genetic resources. Limits on the exploitation of intellectual property rights stem from other fields of law, such as human rights law and international environmental law. Trade-offs may be required where issues such as public access to innovative medicines are at stake. In this regard, compulsory licensing remains an option under the TRIPS agreement for patents in any field. In the 2001 Doha Declaration on TRIPS and Public Health, member governments of the World Trade Organization (WTO) stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health.

#### B *Domestic Regulation, Governance and Oversight*

Domestic regulation, governance and oversight of synthetic biology differs across the world. The workshop presented some information regarding Australia's domestic system, as well as a brief discussion of some other countries/regions as comparators (including China, Canada, the European Union, and the United States). As the information was discussion-based, and not detailed enough to provide a comprehensive review of various domestic approaches to regulating synthetic biology, that such discussion was had is only noted here.<sup>39</sup> However, below are some specific points about Australia and the United States which were found to be useful in highlighting the complexities of current regulatory regimes. Some discussion of what more is needed was had, as well as noting that the drive by both Australia and the United States (as well as the European Union, United Kingdom and China) to engage with the research has been criticised as ignoring (or working against) calls for a moratorium on certain types of research and commercialisation.

#### 1 *Australia*

The current scheme of gene technology regulation in Australia is complex. Live and viable GMOs are regulated in Australia by the Gene Technology Regulator under the *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation. An integrated framework involving other agencies then makes up Australia's gene technology regulatory system (which operates at the Commonwealth level) for regulating GMOs or genetically modified (GM) products. The agencies include:

- Food Standards Australia New Zealand (FSANZ), which is responsible for examining the safety of GM foods (Food Standards Code);
- The Australian Pesticides and Veterinary Medicines Authority (APVMA), which operates the national system that evaluates, registers and regulates all agricultural chemicals (including those that are, or are used on, GM crops) and veterinary therapeutic products under the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals (Administration) Act 1994*;
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which provides a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989*;

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<sup>39</sup> For further discussion of such regulatory regimes see OECD, *Emerging Policy Issues in Synthetic Biology* (OECD Publishing, 2014).

- The Therapeutic Goods Administration (TGA), which administers the *Therapeutic Goods Act 1989* that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products, and ensures their quality, safety and efficacy; and
- The Australian Quarantine and Inspection Service (AQIS), which regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk. Import permit applications must indicate the presence of a GMO and the Office of the Gene Technology Regulator authorisation.

The Gene Technology Ethics and Community Consultative Committee (GTECCC) considers ethical issues raised by synthetic biology to be qualitatively similar to those raised by gene technology. It provided the following information about the GTECCC third face-to-face meeting of the 2011–2014 Triennium in Canberra on 24 May 2013:

[T]he GTECCC noted that whether synthetic biology raises new ethical issues had been discussed by GTECCC at previous meetings. At its sixth meeting in May 2012, GTECCC concluded that synthetic biology did not raise any new ethical issues, and that the known proposed applications of synthetic biology would be regulated under the *Gene Technology Act 2000* ... GTECCC also agreed to maintain a watching brief on developments and reports regarding synthetic biology. At the seventh GTECCC meeting, members were provided with a presentation from a PhD candidate from the Australian National University Law School on research into the ethical and legal issues around synthetic biology and its regulation. Members also received a report on a Scoping Workshop on ‘Synthetic Biology Futures in Australia?’ from an officer from the National Enabling Technology Strategy (NETS). GTECCC noted the updates in the area of synthetic biology and agreed that:

- GTECCC will continue to maintain a watching brief on developments and reports regarding synthetic biology, noting the rapid and ongoing developments in this field;
- most techniques related to synthetic biology to date would be regulated under the Act, noting that this is predicated on the definitions in the legislation. GTECCC understands that the 2011 review of the Act considered the issue of the definitions keeping pace with technological advances, and would be interested in being consulted on future proposals to change the definitions;
- GTECCC notes that synthetic biology in relation to animals is subject to additional regulation by animal ethics committees;
- GTECCC has considered several reports by expert groups that discuss synthetic biology. These reports have comprehensively covered scientific issues and also underline the importance of continuing social and ethical responsibility of scientists;
- the reports all discuss deliberative democracy and emphasize the need not only for public consultation, but for public engagement; and
- GTECCC notes that the context for this issue also includes the debate around traditional intellectual property and the rapid expansion of open access science.<sup>40</sup>

It was further noted at the workshop that an independent review of the *Gene Technology Act 2000* in 2011 recognised that scientific and technological advances in gene technology and biotechnology continue to be rapid. Submissions included suggestions for improvements in regulation — which to date do not appear to have been realised. For example, in their submission to the review, the Department of Innovation, Industry, Science and Research and

<sup>40</sup> See Office of the Gene Technology Regulator, *Gene Technology Ethics and Community Consultative Committee Meeting 24 May 2013 Canberra* (26 August 2013) <<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-comm-May2013-htm>>.

the Commonwealth Scientific and Industrial Research Organisation noted that Australia's regulatory system regarding genetically modified organisms is complex and is in need of simplification; that issues of scale, containment and organisms with multiple modifications may create problems for regulators in the future; that there is a risk of the technology outpacing the regulation; that there is a need to ensure that consultation seeks to actively solicit input beyond the most active interest groups (for example, to the broader community); and that risk assessment should include an assessment of benefits as well as potential negative implications.<sup>41</sup>

The 2013 'All Governments' Response' to the review agreed to undertake further investigation of ways to ensure that the Act remains up to date with advances, including mechanisms to expeditiously amend legislative definitions, exclusions and the scope of regulation.<sup>42</sup> Friends of the Earth have expressed deep concern with Australia's flat rejection of the proposal for a moratorium that was discussed above.<sup>43</sup>

## 2 United States

It was noted at the workshop that the dominant idea in the United States regarding the regulation and governance of synthetic biology is that the existing policy and regulatory framework for biotechnology applies, with minor adaptations, to synthetic organisms. Details of the regulatory system were noted as having been discussed regarding the soft law approach to regulation that dominates the United States environment.

It was further noted that laboratory research is overseen by the National Institute of Public Health (NIPH), and that the NIPH biosafety system for risk assessment and categorisation of biological risk applies to synthetic biology research. This system has served as a reference document for the development of legislation and guidelines worldwide and encompasses the use of biosafety levels 1 to 4. It was again noted that the NIH Recombinant DNA Advisory Committee has concluded that, in most cases, biosafety risks for synthetic nucleic acids are comparable to rDNA research and that the current risk assessment framework can be used to evaluate synthetically produced nucleic acids with attention to the unique aspects of this technology. The NIH Guidelines for research involving rDNA molecules were adapted to specifically cover and provide principles and procedures for risk assessment and management of research involving synthetic nucleic acids. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (for example, a toxin or a pharmacologically active agent) are regulated in the same way as their natural DNA counterpart.

Assessment and regulation of biotechnology products, including their intended environmental releases of organisms, fall under a coordinated framework put in place by the Environmental Protection Agency (EPA), the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration (FDA). This coordinated framework is considered appropriate for regulating most of the organisms obtained by near-term SynBio applications. Challenges and gaps have also been identified in United States regulations. These include that:

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<sup>41</sup> The Department of Innovation, Industry, Science and Research and the Commonwealth Scientific and Industrial Research Organisation, Submission to the Australian Government Department of Health, *2011 Review of the Gene Technology Act (2000)* (2011).

<sup>42</sup> Australian, state and territory governments, 'All Governments' Response to the Recommendations of the 2011 Review of the Gene Technology Act (2000)' (Response, Australian Government Department of Health, 2011).

<sup>43</sup> Louise Sales, 'Throwing Precaution to the Wind: The Government's Attempts to Thwart Regulation of Synthetic Biology' (2014) 122 *Chain Reaction* 18.

- unlike plants obtained by older genetic modification techniques, the engineering of organisms without the use of a (component of a) plant pest would shift them out of the regulatory review of APHIS;
- existing law may not provide the government with the authority to regulate genetically modified plants produced through synthetic biology; and
- it is expected that EPA regulators will face an increased influx of genetically engineered microbes intended for commercial use for which the risk assessment will pose a greater challenge for resources.

There have been proposals in the United States that additional funding, as well as a fast track for low-risk types of microbes, may become necessary in the future. Certain legislative actions that could strengthen the *Toxic Substances Control Act* as it applies to microbes may also become necessary.<sup>44</sup> However, commentators have also noted that although options for regulating synthetic biology within existing legislative authorities have been suggested, '[US] congressional resistance to passing strong environmental legislation of any type probably precludes the passage of new authority for [S]yn[B]io specific regulation'.<sup>45</sup>

## VII CONCLUSION

The regulation and governance of synthetic biology reflects the youth of the field. Not all countries have detailed policy agendas. A number have taken the position that synthetic biology at present falls under the regulatory structures in place that address biotechnology, gene technology, environmental issues and/or human health. However, there are gaps in regulation and governance, and issues about how regulation can keep pace. The indication is that regulators are 'keeping watch' at both national and international levels to assess issues related to this emerging technology. Some scientists have taken significant steps to 'fill the gaps' by designing soft law measures that guide them in their research and practice. Some nations are more concerned, and are calling for a moratorium on certain types of research, release into the environment, and commercial use. As research moves to products, increased regulatory attention may arise.

This report has highlighted some of the promised benefits and perceived perils of synthetic biology. It has detailed the discussion had at the Macquarie University workshop on the ethics and governance of synthetic biology, and presented information about ongoing areas in need of further discussion and exploration. However, this report is not a complete reflection of the issues discussed on the day. The papers, commentaries and notes that follow, written by the distinguished speakers who presented at the workshop on the day and other contributors to the journal, further explore ethical, social, legal and regulatory issues of note. We are all grateful to Macquarie University, the Office of the Deputy Vice Chancellor of Research and the Faculty of Arts for providing a grant to allow us — lawyers, ethicists, philosophers, scientists, members of civil society, industry, government and the community — to come together and join the conversation on the ethics and governance of synthetic biology.

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<sup>44</sup> For discussion of the US regulatory system and options for reform see Sarah R Carter et al, 'Synthetic Biology and the US Biotechnology Regulatory System: Challenges and Options' (Research Report, J Craig Venter Institute, May 2014) 24.

<sup>45</sup> Steve Suppan, *From GMO to SMO: How Synthetic Biology Evades Regulation* (7 August 2014) Institute for Agriculture and Trade Policy <<http://www.iatp.org/documents/from-gmo-to-smo-how-synthetic-biology-evades-regulation>>.

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#### ▼ Alternative Media Edition (1)

- [Macquarie Law Journal](#)
- 1445-386X
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### Lists

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- [Macquarie law journal - \(75824\)](#)
- [Elder Law Revue - \(14561\)](#)

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### ▼ Basic Description

<b>Title</b>	Macquarie Law Journal (Online)
<b>ISSN</b>	1839-373X
<b>Publisher</b>	Macquarie University * School of Law
<b>Country</b>	Australia
<b>Status</b>	Active
<b>Start Year</b>	2001
<b>Frequency</b>	Annual
<b>Language of Text</b>	Text in: English
<b>Refereed</b>	Yes
<b>Serial Type</b>	Journal
<b>Content Type</b>	Academic / Scholarly
<b>Format</b>	Online
<b>Website</b>	<a href="http://www.law.mq.edu.au/law_journals/macquarie_law_journal/">http://www.law.mq.edu.au/law_journals/macquarie_law_journal/</a>
<b>Description</b>	Contains critical and theoretical analysis of legal concepts in their social, cultural and political contexts.

### ▶ Subject Classifications

### ▶ Additional Title Details

### ▶ Publisher & Ordering Details

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