Source: Christine Cooper

F. CONCLUSIONS

Some general principles of international law such as the duty to avoid transboundary harm, and the need to conduct an environmental impact assessment (EIA), together with the rules of State responsibility may provide some guidance relevant to addressing potential negative impacts resulting from the application of synthetic biology techniques, but would still form an incomplete basis to address all potential positive and negative impacts. There exist a range of uncertainties of their application in the absence of specific guidance.

In addition, they may not be able to address the scope of the risks associated with some forms of synthetic biology techniques. Specific potential impacts of specific synthetic biology products might violate particular rules, but this cannot be determined unless there is greater confidence in estimates of such potential impacts.

However, living organisms resulting from current synthetic biology techniques are "living modified organisms resulting from biotechnololgy" as defined by the Convention on Biological Diversity and therefore subject to its biosafety provisions (Articles 8(g) and 19). Living organisms resulting from current synthetic biology techniques also fall under the definition of "living modified organisms" under the Cartagena Protocol for Biosafety. Therefore, the requirements of the Cartagena Protocol pertaining to the transboundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, also apply.

Gaps could occur where components and products resulting from synthetic biology techniques do not fall within the scope of a treaty regime. For example, components and products resulting from synthetic biology techniques that are not living modified organisms will not be subject to the requirements pertaining to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity contained in the Cartagena Protocol, nor the provisions on liability and redress contained in the Nagoya – Kuala Lumpur Supplementary Protocol.

A number of treaties exist which, in general, provide for mechanisms, procedures or institutions that could address potential negative effects associated with the application of synthetic biology techniques, but where no specific guidance exists for their application. For example, States may be able to establish import restrictions on components, organisms and products resulting from synthetic biology techniques in accordance with the SPS Agreement. However, while specific guidance has been developed for the application of standards to living modified organisms, for example in ISPM No. 11 under the IPPC, no such guidance exists for components and products resulting from synthetic biology techniques. In addition, treaties like the SPS Agreement focus mainly on trade-related measures, which may not be sufficient to address all potential risks associated with synthetic biology techniques.

Most regulatory mechanisms discussed in the present document were developed before the term synthetic biology became widely used and therefore they were not intended to cope with the scope and scale that some of the potential impacts of synthetic biology may have, including those with low and very low probability, but very high impacts. The only exception is the Biological Weapons Convention, which prohibits that its parties develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. While some treaties include frameworks for risk assessment, sufficient information may not be available for all synthetic biology techniques to effectively conduct risk assessments. It is a matter of disagreement among synthetic biologists, ecologists, industry and civil society, how well the potential dangers related to synthetic biology are known and can be assessed.

Source: Jeffery Scism

Source: Marcus Kauffman

Synthetic biology also raises a number of questions with regard to access and benefit-sharing. This includes whether the material being accessed for use in synthetic biology can be considered "genetic resources" or "genetic material" and whether the components, organisms and products resulting from synthetic biology constitute "derivatives" as defined in the Nagoya Protocol.

The International Treaty on Plant Genetic Resources for Food and Agriculture may also be relevant to synthetic biology with regard to the access to genetic resources for use in synthetic biology processes and the sharing of the benefits arising from commercialization. Its Article 12 requires parties to provide facilitated access to plant genetic resources for food and agriculture to other parties, including to legal and natural persons under their jurisdiction. This access is to be granted pursuant to a standard material transfer agreement (MTA) through the Multilateral System under certain conditions. Synthetic biology research that does not include chemical, pharmaceutical and/or other non-food/feed industrial uses can access, in accordance with the relevant provisions of the ITPGRFA, the plant genetic resources for food and agriculture listed in Annex I to the Treaty, a pool of 64 food and forage crops. These plant genetic resources and their genetic parts and components cannot be protected through an intellectual property right that limits the facilitated access to them, in the form received from the Multilateral System.

It appears that, in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patents should be available under national law of WTO members (other than LDCs) for innovative products and techniques in the field of synthetic biology, provided that they constitute inventions that comply with the general patentability standards. The results of current synthetic biology research that is focused on modifying existing "natural" genomes could also qualify for the "breeder's right" (a sui generis form of protection for intellectual property rights on plant varieties) under the UPOV Convention. As far as synthetic biology research may in the future result in the production of entirely novel genomes, it may be able to produce new plant varieties which could be protected by breeder's rights, including varieties that are deemed essentially derived from a protected variety.

In sum, the components, organisms and products resulting from synthetic biology would fall under the scope of a number of regulatory mechanisms. While some instruments are sufficiently broad to address some of the current issues related to synthetic biology, gaps still exist relating to the practical implementation of these instruments to ensure the conservation and sustainable use of biodiversity, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources. Discussions in international fora may be needed with a view to addressing the gaps identified in this document in an appropriate, consistent, comprehensive and adaptive manner. This could include a need to consider how to address potential impacts of very low probability but very high magnitude. Further discussions may also be needed if and when the advances in synthetic biology lead to the emergence of new gaps.

Source: Jeffery Scism