TWN Biotechnology & Biosafety Series 18

# Synthetic Biology and Relevant International Law

by Lim Li Ching

TWN
Third World Network

# Synthetic Biology and Relevant International Law

*Lim Li Ching*

TWN
Third World Network
Penang, Malaysia

**Synthetic Biology and Relevant International Law**
is published by
Third World Network
131 Jalan Macalister
10400 Penang, Malaysia.



Printed by Jutaprint
2 Solok Sungei Pinang 3, Sg. Pinang
11600 Penang, Malaysia.

ISBN: 978-967-0747-18-7

# Contents

**Acknowledgement**

The papers in this compilation were originally published by GenØk – Centre for Biosafety, Tromsø, Norway in December 2016, as three chapters in *Biosafety Report 2016/02: Synthetic biology – biosafety and contribution to addressing societal challenges*.

The papers draw on lectures prepared by the author for two courses entitled "Capacity building course: Synthetic biology – biosafety and contribution to addressing societal challenges", with participants from the regions of southern Africa (organized in South Africa in September 2015) and Southeast Asia and China (organized in Indonesia in May 2016). The courses were organized by GenØk, the Norwegian Institute of Bioeconomy (NIBIO) and, respectively, North-West University, South Africa and Bogor Agricultural University, Indonesia.

This compilation updates the papers in light of the outcomes of the December 2016 UN Biodiversity Conference in Mexico, where Parties to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety took decisions relating to synthetic biology.

Chapter 1

# Relevance and Application of the Cartagena Protocol on Biosafety to Synthetic Biology

## Cartagena Protocol on Biosafety

EFFORTS to establish legally binding rules on genetically modified organisms (GMOs) were first introduced onto the international agenda during the discussions leading to the Rio Earth Summit. Finalized in 1992, the Convention on Biological Diversity (CBD), in its Article 19(3), provided governments the mandate to consider the need for a protocol on biosafety to address the risks of genetic engineering.

After long and at times acrimonious negotiations, the Cartagena Protocol on Biosafety was finally concluded in 2000. It entered into force on 11 September 2003 after obtaining the requisite number of ratifications, acceptances, approvals or accessions. It is the first and only international law to specifically regulate genetic engineering and GMOs. (In the Protocol, GMOs are known as living modified organisms or LMOs.)

The Cartagena Protocol is legally binding in the international legal system and in the legal systems of countries that have ratified, approved, accepted or acceded to it. As of October 2016, there were 170 Parties to the Protocol.

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is a separate treaty that deals with the issue of liability and redress for damage resulting from the transboundary movements of LMOs.

**Significance of the Cartagena Protocol**

For the first time in international law, there is recognition that LMOs are inherently different from other, naturally occurring organisms and may carry special risks and hazards, and therefore need to be regulated internationally. The Protocol addresses the fact that LMOs may have biodiversity and human health impacts, and that these impacts need to be risk-assessed. The Protocol also recognizes that socio-economic considerations can be taken into account when making decisions on LMOs, an issue that is particularly significant for developing countries.

Importantly, the Cartagena Protocol puts the Precautionary Principle into operation in decision-making (i.e., in the absence of scientific certainty, a party should err on the side of caution and could restrict or ban the import of LMOs on account of their potential adverse effects) and this further establishes the Principle in international law.

The Protocol deals mainly with the transboundary movement (import and export) of LMOs, including illegal and unintentional transboundary movements. However, its scope extends to all kinds of LMOs, including plants, food, pharmaceuticals, animals, insects, trees, for industrial use, etc.

Its "advance informed agreement" (AIA) procedure governs the first transboundary movement between Parties of LMOs for intentional introduction into the environment. This procedure essentially establishes the principle of prior informed consent, that there should be no export of LMOs unless the importing

country approves its transboundary movement. It also establishes the right of the importing Party to say "no" to a given request for import.

The AIA procedure involves three key steps. First, the Party of import must be notified by the Party of export or the exporter, of the latter's intent to send LMOs. Thus, countries now have an international right to be notified that an LMO is going to be shipped to them.

The Party of import then evaluates the risk assessment which has been submitted by the Party of export or exporter, or alternatively conducts its own risk assessment if it is not satisfied with the risk assessment submitted, which is usually conducted by the developer of the LMO. Risk assessment can take into account the expert advice of and guidelines developed by relevant international organizations. Precaution is also one of the general principles of risk assessment.

Finally, the Party of import makes its decision based on precaution. The decision could be for unconditional approval, approval with conditions, prohibition, a request for additional relevant information or extension of the time period for further consideration of the application.

The AIA procedure thus places obligations on exporting Parties to first seek the informed approval of importing Parties before any transboundary movement can occur. It reverses the burden for importing countries that have little capacity and information to know what is entering into their territories, and to regulate them accordingly. It also affords rights and places corresponding obligations on to importer countries.

However, the Protocol excludes some LMOs – LMOs in transit, in contained use, and that are intended for food, animal feed

or for processing – from the AIA procedure. Nonetheless, they are still covered by the Protocol, and all other provisions apply to these categories of LMOs. For LMOs that are intended for food, animal feed or for processing, a separate procedure applies; countries that make a final decision on domestic use must notify the Biosafety Clearing-House (BCH), a website portal operated by the Secretariat of the CBD.

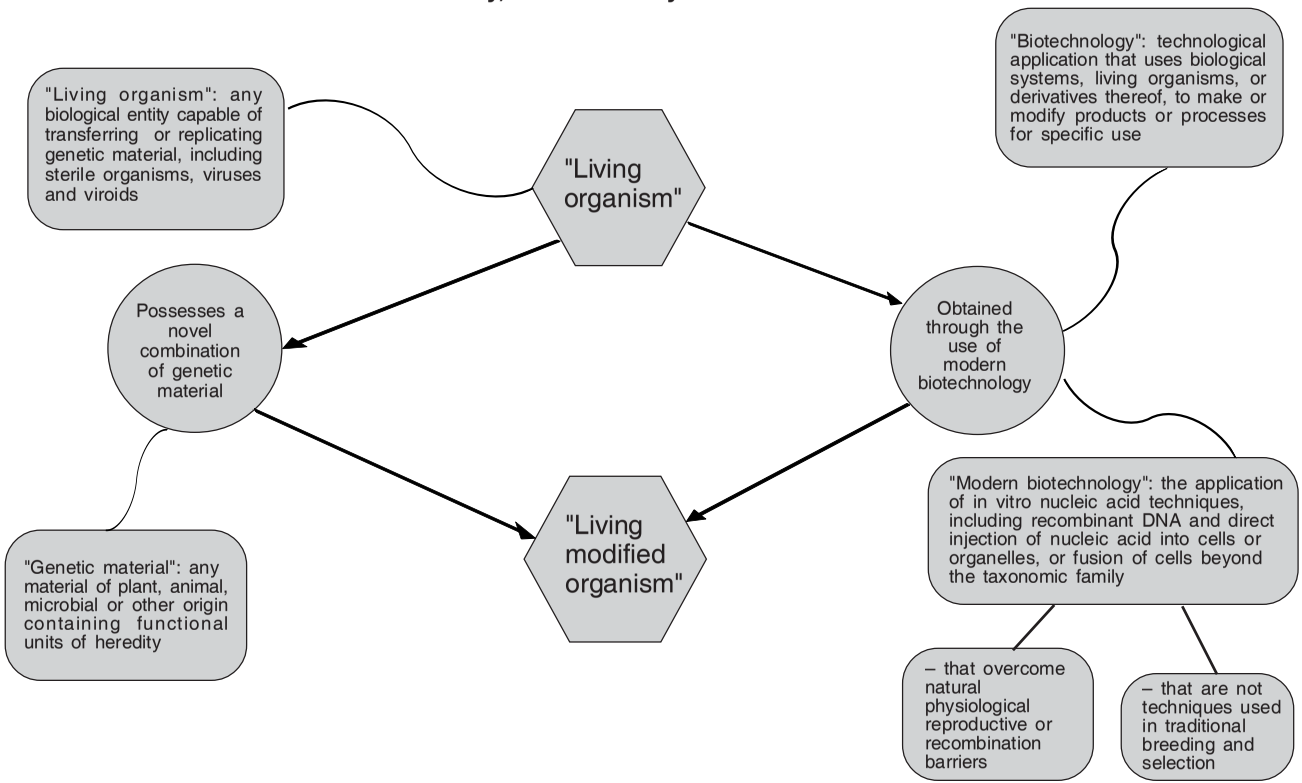
Parties to the Protocol can moreover choose to implement the AIA procedure at the national level in relation to *all* LMOs. Within the domestic regulatory system, this principle can also apply to nationally developed LMOs that undergo an approvals process.

**Definitions**[1]

In order to determine whether or not the organisms, components and products of synthetic biology are addressed by the Cartagena Protocol on Biosafety, it is instructive to explore further some of the definitions under both the Protocol and its parent treaty, the CBD. (See Figure 1 for a schema showing these definitions and their relationship to each other.)

[1] In this section, the interpretations and implications of the text of the Cartagena Protocol are taken from *An Explanatory Guide to the Cartagena Protocol on Biosafety* (2003).

**Figure 1: Schema showing the various definitions found in the CBD and the Cartagena Protocol on Biosafety, and how they relate to each other**



In Article 2 of the CBD, "*biotechnology*" means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". Many of the examples of organisms developed though synthetic biology can thus be considered as "living modified organisms resulting from biotechnology" as defined by the CBD.

Article 3 of the Cartagena Protocol meanwhile provides three definitions that are interrelated and have to be read together: "*living modified organism*", "*living organism*" and "*modern biotechnology*".

Since the scope of the Protocol (Article 4) applies to "all living modified organisms", we need to understand how these are defined in the Protocol.

"*Living modified organism*" means "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology".

A living modified organism is thus defined in the Protocol to include only those living organisms that

- contain novel combinations of genetic material; and
- have been produced using the techniques of modern biotechnology (paragraph 208, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (2003)).

"*Living organism*" means "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids". The specific mention of viruses, viroids and sterile organisms ensures that such entities – which cannot actively replicate genetic material or reproduce through sexual reproduction – are also covered by the Protocol (paragraphs 204 and 205, *Explanatory Guide*). Plasmids and

naked DNA are not included, but where a novel combination of genetic material is introduced through the use of naked DNA or plasmids through modern biotechnology, then the resultant organism would qualify as an LMO. Similarly, the definition would cover a living organism in which a plasmid created by modern biotechnology and that contains a novel combination of genetic material is present, even where the plasmid is not integrated into the chromosomes of that organism (paragraphs 206 and 207, *Explanatory Guide*).

While the Cartagena Protocol does not define "*genetic material*", the CBD does: "any material of plant, animal, microbial or other origin containing functional units of heredity". Functional units of heredity are understood to be nucleic acids containing genetic information. These nucleic acids may be of plant, animal, microbial or other origin. In addition, the definition also covers *an*y material of plant, animal, microbial or other origin, such as whole organisms or parts of organisms, which contains nucleic acids that contain genetic information (paragraphs 198 and 199, *Explanatory Guide*). In the context of the Cartagena Protocol, genetic material can be understood to refer to nucleic acids that contain functional units of heredity (paragraph 201, *Explanatory Guide*).

A "novel combination of genetic material" can be regarded as a combination that was not previously known to exist at the time it was first produced. Linked to the CBD definition of genetic material, this can then be understood to refer to a novel combination of nucleic acid containing functional units of heredity (paragraph 209, *Explanatory Guide*). It is important to note that the novel combination relates solely to a combination of genetic material, even if this does not result in an observational change (paragraph 210, *Explanatory Guide*).

The novelty of a combination could arise through a novel form of a functional unit of heredity, e.g., resulting from a change that modifies the overall sequence of nucleotides within the unit, whether by altering, inserting or deleting one or more nucleotides. Novelty could also arise from a novel arrangement of functional units of heredity, e.g., introduction of genetic material from different species, or rearrangement of genetic material of the same species. A novel combination could arise from a single change in a nucleotide sequence or from much larger changes (paragraphs 211-212, *Explanatory Guide*).

According to the Cartagena Protocol, the novel combination of genetic material must be "obtained through the use of modern biotechnology". This is a fundamental criterion for the definition of an LMO. Whether or not an organism is an LMO under the Protocol depends on whether "modern biotechnology" is used to create a novel combination of genetic material. Furthermore, even if the novel combination of genetic material obtained through modern biotechnology is subsequently transferred into another organism through traditional breeding or selection techniques, the resulting organism is also an LMO under the Protocol (paragraph 214, *Explanatory Guide*). A good example of such LMOs are stacked LMOs as a result of crosses between two or more LMOs.

"*Modern biotechnology*" is defined in the Cartagena Protocol as:

"The application of:

a. In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection".

This therefore includes, but is not limited to, in vitro nucleic acid techniques applied to the insertion, deletion and alteration of genetic material (paragraph 215, *Explanatory Guide*). The two qualifications are that natural physiological reproductive or recombination barriers must be overcome, and that they are not techniques used in traditional breeding and selection.

The negotiators of the Cartagena Protocol recognized that any definition of modern biotechnology should cover new techniques not yet envisaged at the time that the Protocol was adopted but which may emerge in the future. This is because the technology is developing all the time, and the legal instrument had to be drafted so as to not exclude new technological processes not yet identified but which may give rise to novel combinations of genetic material through the use of modern biotechnology. Therefore the definition in Article 3(i) seeks to reflect the need to cover future techniques, by using the wording "in vitro nucleic acid techniques", giving two *existing* examples (i.e., recombinant DNA and direct injection of nucleic acids) and leaving open whether new techniques will be regarded as "in vitro nucleic acid techniques" or not, and by referring to fusion of cells (paragraphs 217-218, *Explanatory Guide*).

**How does the Cartagena Protocol on Biosafety apply to synthetic biology?**

Given the discussion above, and the definitions contained both in the CBD and in the Cartagena Protocol, it is clear that these definitions would apply to most of the living organisms resulting from current synthetic biology techniques. This means that the relevant provisions of both the CBD and the Cartagena Protocol would apply to synthetic biology.

Under the CBD, its biosafety provisions relating to LMOs are found in Articles 8(g), 19(3) and 19(4). Under Article 8(g), where

LMOs resulting from biotechnology are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, Parties are required, as far as possible and as appropriate, to establish or maintain means to regulate, manage or control these risks at a national level.

Article 19(3) was the enabling provision that gave rise to the Cartagena Protocol by obliging Parties to consider the need for and modalities of a protocol in the field of the safe transfer, handling and use of LMOs.

Article 19(4) obliges Parties to provide any available information about the use and safety regulations in handling LMOs, as well as any available information on the potential adverse impact of the specific organisms concerned to a Party into which these LMOs are to be introduced.

At the same time, all the provisions of the Cartagena Protocol apply to living organisms resulting from synthetic biology that fulfil the criteria of possessing a novel combination of genetic material and obtained through the use of modern biotechnology.

Therefore, discussions on synthetic biology have been ongoing under both the CBD and the Cartagena Protocol. In particular, the CBD established an Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology in 2014. The AHTEG, which met in September 2015, agreed an operational definition of synthetic biology to assist Parties in their implementation of the provisions of the CBD: "Synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems."

The AHTEG also concluded that living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, are similar to living modified organisms as defined in the Cartagena Protocol. Parties to the CBD, at the Thirteenth Conference of the Parties (COP 13) in December 2016, took note of this conclusion in Decision XIII/17.

Parties also noted in Decision XIII/17 that "it is not clear, given the current state of knowledge, whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the definition of living modified organisms under the Cartagena Protocol, and further notes that there are cases in which there may be no consensus on whether the result of a synthetic biology application is 'living' or not".

One issue under discussion is that of components and products of synthetic biology, given that the scope of the Cartagena Protocol applies to *living* modified organisms. The CBD Secretariat and AHTEG on Synthetic Biology refer to "components" as parts used in a synthetic biology process (e.g., a DNA molecule), and "products" as the resulting output of a synthetic biology process (e.g., a chemical substance), and consider "components" and "products" as non-living.

However, the Cartagena Protocol does address "products thereof" in a limited way, under provisions and annexes addressing information sharing and risk assessment. Products thereof are "processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology". For example, specific compounds such as specialized chemicals, fuels, flavours and pharmaceuticals produced by microorganisms that have been altered by synthetic biology techniques may also fall within the Protocol's

definition of "products thereof" if they contain nucleic acids containing a novel combination of genetic material (Secretariat of the Convention on Biological Diversity, 2015).

Article 20 of the Cartagena Protocol requires Parties to make the summaries of risk assessments, including relevant information regarding products thereof, available on the Biosafety Clearing-House, the information-sharing website administered by the CBD Secretariat. Annex I, which details the information required in notifications, includes products thereof, while Annex III, which is the Protocol's general framework on risk assessment, is applicable to products thereof.

Likewise, while naked DNA and its constituent parts resulting from synthetic biology are not included in the definition of living organisms (see earlier discussion) under the Cartagena Protocol, they would be addressed as "products thereof" if they contain detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology. Furthermore, if novel DNA is inserted into living cells for shipment, the cells themselves would qualify as "living organisms" and hence be covered by the Protocol, as they would contain novel combinations of genetic material and would have been produced using the techniques of modern biotechnology (Secretariat of the Convention on Biological Diversity, 2015).

In any case, national laws may specifically regulate products and components of synthetic biology. It is worth recalling that the Protocol is a negotiated international law framework that sets minimum standards for national biosafety implementation. This is clearly established in Article 2(4) of the Cartagena Protocol: "Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than called for in this Protocol, provided that such

action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law." Sovereign countries interpret and implement the Cartagena Protocol, and can do so in a comprehensive manner, and with higher standards for biosafety.

At the current juncture of development of synthetic biology, many of the applications are still at the laboratory research stage. It is thus also worth remembering that Article 6 of the Protocol, while exempting LMOs destined for contained use from the AIA procedure, preserves the right of Parties to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within their jurisdiction.

## References


*An Explanatory Guide to the Cartagena Protocol on Biosafety* (2003). IUCN Environmental Policy and Law Paper No. 46. International Union for the Conservation of Nature and Natural Resources: Gland, Switzerland and Cambridge, UK. https://bch.cbd.int/database/attachment/?id=10858

Cartagena Protocol on Biosafety (2000). Secretariat of the Convention on Biological Diversity, Montreal.

Convention on Biological Diversity (1992). Secretariat of the Convention on Biological Diversity, Montreal.

Decision XIII/17. Synthetic biology. CBD/COP/DEC/XIII/17, 16 December 2016.

Report of the Ad Hoc Technical Expert Group on Synthetic Biology (2015). UNEP/CBD/SYNBIO/AHTEG/2015/1/3, 7 October 2015.

Secretariat of the Convention on Biological Diversity (2015). *Synthetic biology.* Montreal, Technical Series No. 82. https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf

Chapter 2

# Synthetic Biology and Relevant International Laws: Gaps and Overlaps

## Introduction

"SYNTHETIC biology" as such has not been addressed specifically in the text of any multilateral treaties. However, there are a multitude of treaties, customary rules and general principles of law, as well as other regulatory instruments and mechanisms, which could apply to all or some forms of synthetic biology.

The treaties could apply to issues such as:

- The transfer and handling of components, organisms and products resulting from synthetic biology techniques;
- The use of components, organisms and products resulting from synthetic biology techniques for a specific purpose, in particular for hostile purposes or in armed conflict;
- Intellectual property rights associated with components, organisms and products resulting from synthetic biology techniques, e.g., patentability; and
- Access to genetic resources used in synthetic biology techniques, and sharing of benefits arising from their utilization (Secretariat of the Convention on Biological Diversity, 2015).

The Secretariat of the CBD produced a comprehensive publication addressing the potential impacts of synthetic biology

on biological diversity, and the gaps and overlaps with the provisions of the Convention and other agreements. This document was published in 2015 as CBD Technical Series No. 82. This chapter summarizes the key findings of the document on the international regulatory regime applying to synthetic biology. It aims to provide an overview of the international treaties and fora that are relevant, and where the remaining gaps are.

## Synthetic biology, the CBD and the Cartagena Protocol on Biosafety

From the discussion on definitions in the preceding chapter, the CBD and its Protocols have a clear and overarching mandate on synthetic biology.

### *Convention on Biological Diversity*

In terms of the conservation and sustainable use of biological diversity, Article 14 of the CBD obliges Parties to conduct environmental impact assessment for activities that are likely to have significant impacts on biological diversity with a view to avoiding or minimizing such effects.

The biosafety provisions regarding "living modified organisms resulting from biotechnology" are in Articles 8(g), 19(3) and 19(4) of the CBD, as discussed in the preceding chapter, and would therefore apply to synthetic biology. These broadly oblige Parties to establish or maintain means to regulate, manage or control risks at a national level, ensure safe transfer, handling and use, and provide available information about the use and safety regulations and potential adverse impacts.

As such, synthetic biology has been discussed under the CBD since 2010. In Decision X/13, Parties, other Governments and relevant organizations were invited to apply the precautionary

approach to the field release of synthetic life, cell or genome into the environment.

In 2012, Decision XI/11 recognized the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity. The decision urged Parties and invited other Governments to take a precautionary approach when addressing threats of significant reduction or loss of biological diversity posed by synthetic biology organisms, components and products. It also noted, based on the precautionary approach, the need to consider the potential positive and negative impacts of synthetic biology components, organisms and products, and initiated a process by which synthetic biology could be considered by the CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).

A precautionary approach to synthetic biology was again reaffirmed in 2014. Decision XII/24 further urged Parties and invited other Governments, inter alia, 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; to approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out; and to carry out scientific assessments of synthetic biology organisms, components and products that consider risks to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations; and that such assessments should be done with, where appropriate, the full participation of indigenous and local communities.

The issue of synthetic biology was once again on the agenda for the CBD Conference of the Parties (COP 13) in December

2016. Work has progressed with the establishment of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology (see box) and the issue will continue to be discussed and elaborated in the coming years, particularly as COP 13 extended the mandate of the current AHTEG, with new terms of reference (see box).

**Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology**

The CBD Conference of the Parties (COP) in 2014 established an Ad Hoc Technical Experts Group (AHTEG) on Synthetic Biology (Decision XII/24). Preceded by an online forum that involved hundreds of experts to discuss key issues, the AHTEG met in September 2015. A peer review of the AHTEG outcomes was held in November 2015 and the AHTEG recommendations were considered by the twentieth meeting of SBSTTA in April 2016.

The terms of reference for the AHTEG asked it to, among others:

- Identify the similarities and differences between LMOs (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques to determine if LMOs derived from synthetic biology fall under the scope of the Cartagena Protocol;
- 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;
- Work towards an operational definition of synthetic biology;
- 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 socio-economic impacts relevant to the mandate of the Convention and its Protocols;
- 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; and
– 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 CBD and its Protocols, in particular threats of significant reduction or loss of biological diversity.

At COP 13 in December 2016, Parties to the CBD considered the SBSTTA report and negotiated a new decision on synthetic biology (Decision XIII/17) which, among other things, extended the mandate of the current AHTEG with new terms of reference, which include the following:

– Review recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts;
– Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol;
– Further analyze evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-a-vis the three objectives of the Convention, and gather information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology;
– In order to avoid or minimize any potential negative effects on the conservation and sustainable use of biodiversity, evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology; and
– Provide, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at a meeting held prior to the fourteenth meeting of the Conference of the Parties, recommendations on the basis of its deliberations to facilitate future discussions and actions on synthetic biology under the Convention.

### *Cartagena Protocol on Biosafety*

CBD Technical Series No. 82 stresses that living organisms resulting from current synthetic biology techniques fall under the definition of "living modified organisms" under the Cartagena Protocol for Biosafety. Currently, as living organisms resulting from synthetic biology techniques fulfil the criteria of (i) being a living organism, (ii) possessing a novel combination of genetic material, and (iii) resulting from the use of modern biotechnology, the Cartagena Protocol on Biosafety is fully applicable to them. Therefore, its requirements pertaining to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, apply. (See the preceding chapter for a more detailed discussion on the Cartagena Protocol.)

This may need to be reassessed if and when future technological advances of synthetic biology lead to the creation of living organisms possessing novel combinations of genetic material which are heritable and do not result from the use of in vitro nucleic acid techniques or cell fusion (Secretariat of the Convention on Biological Diversity, 2015).

It should also be noted that the AHTEG on Synthetic Biology, established by the CBD Parties, has concluded that living organisms developed through current applications of synthetic biology, or that are currently in the early stages of research and development, are similar to living modified organisms as defined in the Cartagena Protocol. Parties to the CBD, at COP 13, took note of this conclusion in Decision XIII/17.

While the conversation on the components and products of synthetic biology under the Cartagena Protocol is more nuanced (see preceding chapter for a more detailed discussion), it should

be noted that they do in any case fall within the scope of the CBD and its objectives.

The Cartagena Protocol does contain some limited exemptions of some LMOs from some provisions. The Protocol does not apply to the transboundary movement of LMOs which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations (Article 5). Some examples of LMOs produced through synthetic biology that are pharmaceuticals for humans are live virus vaccines. However, as none of the organisms currently produced through synthetic biology that are intended to be used as pharmaceuticals for humans are directly addressed by other relevant international agreements or organizations, they therefore would arguably fall under the Cartagena Protocol's scope (Secretariat of the Convention on Biological Diversity, 2015).

Moreover, where synthetic biology organisms are used as "biofactories" to produce pharmaceuticals such as in the case of artemisinin, the organisms themselves are not pharmaceuticals, but they are still LMOs produced by synthetic biology and would therefore be covered by the Cartagena Protocol (Secretariat of the Convention on Biological Diversity, 2015). LMOs produced by synthetic biology that are pharmacueticals for animals would clearly not be exempted from the Protocol.

Some organisms resulting from synthetic biology techniques may fall under exemptions from the Cartagena Protocol's advance informed agreement provisions for LMOs, for example, if they are in transit, intended for contained use or for direct use as food or feed, or for processing.

Nonetheless, Article 6 of the Protocol preserves the right of a Party to regulate the transport of LMOs through its territory,

and to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction. Similarly, a Party may take a decision on the import of LMOs intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of the Protocol. Many such national frameworks require advance informed agreement for LMOs intended for direct use as food or feed, or for processing.

In addition, once entered into force, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety will require Parties to provide at the national level for rules and procedures that address damage from LMOs, including those resulting from synthetic biology techniques, where such damage falls under the definition set out in Article 2 of the Supplementary Protocol (Secretariat of the Convention on Biological Diversity, 2015). It is possible that LMOs resulting from synthetic biology techniques could cause adverse effects on the conservation and sustainable use of biological diversity, as described in CBD Technical Series No. 82.

**Other international treaties relevant to synthetic biology**

***Treaties that address specific uses***

*Biological Weapons Convention*

The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, commonly known as the Biological Weapons Convention, addresses microbial or other biological agents or toxins, including those that are components, organisms and products resulting from synthetic biology techniques. It provides a forum where further guidance for this aspect of synthetic biology could be developed.

The core obligation is for Parties to never in any circumstances develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes. Given that synthetic biology has the potential for dual use, the issue has been discussed explicitly under the Biological Weapons Convention. However, as of 2015, no concrete steps towards the development of an oversight framework, guiding principles or models to inform risk assessment and oversight of scientific research have been undertaken (Secretariat of the Convention on Biological Diversity, 2015).

*SPS Agreement*

Some applications of synthetic biology could also, depending on the specific case, be considered as causing risks to animal or plant life or health arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; or as risks to human or animal life or health arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs (Secretariat of the Convention on Biological Diversity, 2015).

If this is the case, measures taken by member states of the World Trade Organization (WTO) to address these risks would count as sanitary and phytosanitary measures in the sense of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and would have to comply with the requirements thereof. Any measures taken would have to be based on a risk assessment and scientific principles, must not unjustifiably discriminate on other WTO members' exports and must not be more trade-restrictive than necessary to achieve the appropriate level of protection.

The SPS Agreement explicitly recognizes the international standards, guidelines and recommendations developed by the

Codex Alimentarius Commission, World Organization for Animal Health (OIE) and the International Plant Protection Convention. The standards set by these bodies may be relevant to components, organisms and products resulting from synthetic biology (Secretariat of the Convention on Biological Diversity, 2015).

Guidance exists as to the application of the standards to LMOs, although it is not clear how these standards could be applied for all forms of synthetic biology techniques (Secretariat of the Convention on Biological Diversity, 2015). The standard-setting organizations have not, as yet, explicitly addressed synthetic biology.

***Treaties that address access and benefit-sharing***

*Convention on Biological Diversity*

In cases where synthetic biology requires access to genetic resources, the access and benefit-sharing requirements of the CBD would, in general, apply and thus require prior informed consent (unless otherwise determined) and the negotiation of mutually agreed terms (Secretariat of the Convention on Biological Diversity, 2015). Parties are also obliged to take legislative, administrative or policy measures with the aim of sharing in an equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing such resources.

*Nagoya Protocol on Access and Benefit-Sharing*

Synthetic biology applications may also be considered as a way of utilizing genetic resources, as defined in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. National

implementation and the negotiation of mutually agreed terms would assist parties to access and benefit-sharing agreements to clarify to what extent of the value chain the obligations to share benefits would continue to apply to the organisms, components and products of synthetic biology, including derivatives and their subsequent applications (Secretariat of the Convention on Biological Diversity, 2015).

Components used in synthetic biology include virtual/digital information on functional units of heredity. In this context, it is not clear whether virtual/digital information about genes and other genetic elements can be considered "genetic resources" or "genetic material" in accordance with the definitions contained in Article 2 of the CBD (Secretariat of the Convention on Biological Diversity, 2015). It is also unclear whether the components used in synthetic biology and the products thereof may be considered "genetic resources" as defined by the Convention (Secretariat of the Convention on Biological Diversity, 2015).

However, the combination of faster genome sequencing with rapid DNA synthesis and powerful gene editing techniques is creating new avenues for biopiracy that must be urgently addressed. The combination of these synthetic biology techniques could undermine implementation of the CBD's access and benefit-sharing obligations, including the Nagoya Protocol. Genetic resources – whether a DNA sequence of specific interest or even entire microorganisms and other small genomes – may now be transferred digitally and synthesized into living matter without physical exchange of biological material.

This issue needs to be urgently addressed and was discussed at COP 13 in December 2016. Parties to the CBD took a decision (Decision XIII/17) that sets in motion a plan intended to lead to an important decision at the next COP meeting in 2018. The

plan is a compromise that emerged after developing countries proposed that COP 13 adopt a decision clarifying that sequence information should be treated equivalently to physical biodiversity samples for the purposes of benefit-sharing. The resulting process will collect views from Parties and prepare a fact-finding study. An AHTEG will then consider the results as well as deliberate on several other issues, and report to the next SBSTTA meeting in 2017, which will then forward recommendations to COP 14 in 2018.

*International Treaty on Plant Genetic Resources for Food and Agriculture*

With regard to access to plant genetic resources for use in synthetic biology processes and the sharing of the benefits arising from commercialization, the International Treaty on Plant Genetic Resources for Food and Agriculture may be particularly relevant (Secretariat of the Convention on Biological Diversity, 2015). The Treaty is recognized as one of the complementary instruments that constitute the international regime on access and benefit-sharing. The Treaty's Multilateral System for Access and Benefit-Sharing covers plant genetic resources for food and agriculture listed in its Annex 1. According to CBD Technical Series No. 82, some of these Annex 1 crops are the focus of synthetic biology research.

***Treaties that address intellectual property***

*TRIPS Agreement*

In accordance with the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), patents should be available under national law of WTO members (other than least developed countries) for innovative products and techniques in the field of synthetic biology, provided that they constitute inventions that comply with the

general patentability standards (Secretariat of the Convention on Biological Diversity, 2015).

Select products of synthetic biology techniques may fall under the subject matter exclusions provided by Article 27, paragraphs 2 and 3 of the TRIPS Agreement and may therefore be excluded from patentability by some WTO members (Secretariat of the Convention on Biological Diversity, 2015). Paragraph 2 of Article 27 allows WTO members to provide this exclusion if it is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health, or to avoid serious prejudice to the environment. Some synthetic biology applications may well meet these criteria in some countries, which could provide grounds for their exclusion from patentability.

Furthermore, paragraph 3 of Article 27 of the TRIPS Agreement allows WTO members to exclude the following from patentability: diagnostic, therapeutic and surgical methods for the treatment of plants and animals; plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

*UPOV Convention*

The results of current synthetic biology research that is focused on modifying existing "natural" genomes could also qualify for the "breeder's right" (a form of protection for intellectual property on plant varieties) under the International Convention for the Protection of New Varieties of Plants (UPOV) (Secretariat of the Convention on Biological Diversity, 2015).

## Gaps in the current regulatory framework

The preceding section, drawing on CBD Technical Series No. 82, provided a brief overview of the numerous international treaties that are applicable to various aspects of synthetic biology. In summary, a number of treaties exist which, in general, provide for mechanisms, procedures or institutions that can address potential negative effects associated with the application of synthetic biology techniques (Secretariat of the Convention on Biological Diversity, 2015). However, there is no specific guidance for their application.

While 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, this would still form an incomplete basis to address all potential negative impacts (Secretariat of the Convention on Biological Diversity, 2015). CBD Technical Series No. 82 recommends that discussions in international fora may be needed with a view to addressing the gaps identified 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 with very high magnitude. Further discussions may also be needed if and when the advances in synthetic biology lead to the emergence of new gaps (Secretariat of the Convention on Biological Diversity, 2015).

Nonetheless, from the discussion in the previous section, it is clear that the components, organisms and products resulting from synthetic biology do fall under the scope of a number of international 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 (Secretariat of the Convention on Biological Diversity, 2015).

The CBD and its Protocols provide fairly comprehensive coverage but there are still gaps remaining. Work needs to continue in these fora to fully articulate to what extent they apply to synthetic biology, and how implementation should proceed. In particular, even though the requirements of the Cartagena Protocol apply to most, if not all, organisms resulting from current synthetic biology techniques, it may still be necessary, for example, to identify elements of risk assessment methodologies that would be specific for living organisms developed through synthetic biology in order to ensure the effective application of its risk assessment provisions (Secretariat of the Convention on Biological Diversity, 2015).

Such discussions have started to take place in the AHTEG on Synthetic Biology under the CBD, and the AHTEG on Risk Assessment and Risk Management under the Cartagena Protocol, and synthetic biology will clearly continue to be discussed at the meetings of the CBD and its Protocols, particularly given progress in the COP 13 discussions on synthetic biology and the extension of the mandate of the AHTEG on Synthetic Biology.

However, the AHTEG on Risk Assessment and Risk Management under the Cartagena Protocol, which was expected to develop risk assessment guidance for LMOs developed through synthetic biology, was dissolved. The fate of further work on risk assessment by a possible new AHTEG will be decided by the next Conference of the Parties serving as the Meeting of the Parties (COP-MOP) to the Cartagena Protocol

in 2018. Further specific risk assessment guidance on LMOs produced through synthetic biology, even though requested by Parties, will no longer be automatically considered for further work. This gap needs to be urgently addressed.

## References


Decision X/13. New and emerging issues. UNEP/CBD/COP/DEC/X/13, 29 October 2010.

Decision XI/11. New and emerging issues relating to the conservation and sustainable use of biodiversity. UNEP/CBD/COP/DEC/XI/11, 5 December 2012.

Decision XII/24. New and emerging issues: synthetic biology. UNEP/CBD/COP/DEC/XII/24, 17 October 2014.

Decision XIII/17. Synthetic biology. CBD/COP/DEC/XIII/17, 16 December 2016.

Report of the Ad Hoc Technical Expert Group on Synthetic Biology (2015). UNEP/CBD/SYNBIO/AHTEG/2015/1/3, 7 October 2015.

Secretariat of the Convention on Biological Diversity (2015). *Synthetic biology.* Montreal, Technical Series No. 82. https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf

Chapter 3

# Principles for a Holistic Regulatory Approach to Synthetic Biology

## Potential adverse effects of synthetic biology

THE issue of regulation arises out of the need to avoid or minimize the potential adverse effects that could occur from the release of organisms, components or products of synthetic biology. These effects could be direct or indirect, intended or unintended, as well as immediate or delayed effects. The effects could occur at the genetic, population or ecosystem level.

The Ad Hoc Technical Expert Group on Synthetic Biology in 2015 grouped the following (non-exhaustive) effects according to the impacts on the three objectives of the CBD:

### *Objective 1: Conservation of biological diversity*

- Engineered fitness advantage may lead to invasiveness
- Enhanced gene flow that leads to loss of biodiversity
- Increased pathogenic potential
- Increased levels of toxic substances, which may be disruptive to soil, food-webs and pollinators
- Negative effects on non-target organisms, such as pollinators
- Changes in organisms on the level of basic metabolic pathways, such as altered photosynthesis pathways, carbohydrate metabolism or nitrogen fixation, which may lead to changes in agricultural practice and land use

- Applications aimed at altering and replacing natural populations (for example, gene drive systems) may have adverse effects at the ecosystem level

*Objective 2: Sustainable use of biological diversity*

- Increased demand for biomass crops, as well as changes in patterns of extraction of biomass, minerals and other sources of energy, may lead to changes in land use
- Replacement of natural products may lead to changes in the agricultural practices of communities, which may adversely affect traditional crops, practices and livelihoods
- Gene flow may lead to adverse effects on agrobiodiversity

*Objective 3: Equitable sharing of the benefits of biological diversity*

- Loss of market share and income by indigenous/local communities due to altered exploitation of genetic resources
- Shift in the understanding of what constitutes a genetic resource and the implications thereof, such as the misappropriation of the original source of the DNA information, and if benefits are derived from the use of such DNA information without prior informed consent and mutually agreed terms, the fair and equitable sharing of the benefits would not be possible
- Inappropriate access without benefit-sharing due to the use of sequenced data without material transfer agreements under the Nagoya Protocol
- Patent-driven and open-source approaches to synthetic biology may have different implications in the context of access and benefit-sharing
- Indigenous peoples and local communities will not necessarily support or benefit from the utilization of genetic resources in synthetic biology

**Challenges for risk assessment**

Given the potential adverse effects of synthetic biology, risk assessment becomes a central issue. As the current and near-term applications of synthetic biology build on techniques of modern biotechnology to create organisms with novel combinations of genetic material, it is expected that the general risk assessment methodology for LMOs would be applicable to organisms developed through synthetic biology (Secretariat of the Convention on Biological Diversity, 2015).

However, as outlined in the submission of views by Parties to the CBD on synthetic biology (UNEP/CBD/SYNBIO/AHTEG/2015/1/2), while the potential adverse effects of synthetic biology are similar to those of 'classical' genetic engineering, it can be expected that the former will be broader and more intense due to the ability of synthetic biology to engineer more complex systems for use in a wider range of applications. Moreover, there are likely to be higher levels of scientific uncertainty associated with synthetic biology, due to the higher levels of complexity involved. For example, synthetically modified organisms are likely to have larger segments of modified DNA or even complete novel genomes. Synthetic biology could also lead to the development of new biological systems that do not exist in nature.

In future, as highlighted by some submissions, organisms could be developed through synthetic biology that will fundamentally differ from naturally occurring organisms, making it impossible to conduct risk assessments based on a comparative principle, due to the lack of appropriate comparators.

Risk assessment may therefore be more challenging for synthetic biology, as the complexity of organisms increases, as novel gene sequences are more significantly modified, and as genetic components are assembled from a greater variety of

sources. Future developments in synthetic biology will further raise specific challenges and limitations with regard to risk assessment principles and methodologies that are currently applied to evaluate LMOs. For example, if and when future commercial synthetic biology applications evolve to use techniques that do not rely on in vitro manipulation of nucleic acids to cause inheritable changes, current LMO risk assessment methodologies may no longer be suitable (Secretariat of the Convention on Biological Diversity, 2015).

In practice, while existing approaches of risk assessment, management and communication can be used as a basis for assessing and mitigating the impacts of synthetic biology organisms, some Parties were of the view that guidelines and methodologies would need to be developed and made available to address the additional uncertainties and knowledge gaps. As such, risk assessment methodologies that are currently in use will need to be revised and adapted to ensure that the risks of synthetic biology are adequately addressed. Specific consideration will also likely be needed to identify any gaps that exist in the current LMO risk assessment methodologies, and guidance needed on how to fill such gaps (Secretariat of the Convention on Biological Diversity, 2015).

Due to the complexity and novelty of the organisms developed through new technologies such as synthetic biology, the type and depth of information that may be required to assess their risks will likely differ from the information typically provided by developers for conducting risk assessments of LMOs (Eckerstorfer et al., 2014). The availability of appropriate (case-specific) scientific data is crucial for an adequate risk assessment of organisms, components and products of synthetic biology with a potential for adverse effects or an unknown level of risk for unintended effects. The general challenge is to keep up with the rapid pace of development, and efforts should be made to address the relevant risk issues by appropriate

biosafety research (Eckerstorfer et al., 2014). There may also be a need for a revised risk assessment framework to address the possible novel risks posed by products of synthetic biology whereby no parent organism can be used as comparators.

Given the acknowledged challenges for risk assessment that could be posed by synthetic biology, the AHTEG on Risk Assessment and Risk Management, established under the Cartagena Protocol on Biosafety, discussed the issue in 2016. This was preceded by discussions in the Open-Ended Online Expert-Forum on Risk Assessment and Risk Management.

The AHTEG developed an outline of guidance on "Risk Assessment of LMOs developed through synthetic biology", and the issue was discussed at the Eighth Conference of the Parties serving as the Meeting of the Parties (COP-MOP 8) to the Cartagena Protocol in December 2016. Parties to the Protocol were asked to consider establishing a process for the development of guidance on the basis of the outline developed, in coordination with relevant processes under the CBD.

Regrettably, progress on this issue was stalled at COP-MOP 8. As mentioned in the preceding chapter, the AHTEG on Risk Assessment and Risk Management was dissolved and the fate of further work on risk assessment by a possible new AHTEG will be decided by the Parties to the Cartagena Protocol in 2018. Further specific risk assessment guidance on LMOs produced through synthetic biology, even though requested by Parties, will no longer be automatically considered for further work. This gap needs to be urgently addressed, given the acknowledged challenges for risk assessment posed by synthetic biology and the need for further guidance.

**Outlook and possible elements for a way forward**

According to the synthesis of views submitted by Parties to the CBD on synthetic biology (UNEP/CBD/SYNBIO/AHTEG/2015/1/2), there are several possible elements for a way forward on the governance and regulation of synthetic biology. This would include the need for an open legal framework and transparency to foster awareness by the public and oversight by an informed collection of governments worldwide. Scientific and technological developments in the field of synthetic biology must be reviewed regularly and action taken, particularly if voluntary codes or current regulatory procedures appear insufficient.

In accordance with existing COP decisions, there is agreement that the precautionary approach should be applied to synthetic biology. As such, some Parties are of the view that the environmental and commercial release of organisms resulting from synthetic biology must not occur until procedures and regulatory processes or international regulatory frameworks are in place to ensure the protection of ecological systems.

Many submissions agreed that collaboration with other national and international bodies is needed given the wide-ranging nature and reach of synthetic biology. Of particular importance is the need for a coordinated approach between the CBD and its Protocols, in particular, but not limited to, ensuring strong synergy between the programmes of work on risk assessment and risk management under the Cartagena Protocol and that on synthetic biology under the Convention. The creation of an online platform to facilitate exchange of information on synthetic biology and capacity building would be beneficial in terms of fostering closer collaboration and coordination.

While there is general agreement among the submissions that existing frameworks can be used as a basis for the risk assessment of organisms developed through synthetic biology, specific guidelines are still needed to address the additional complexity and risks posed by synthetic biology organisms. As such, it is proposed that there should be review and adaptation of existing frameworks for risk assessment of LMOs. In addition, the need to develop an international framework on synthetic biology that also provides for an assessment of the cultural and socio-economic impacts was identified.

***AHTEG recommendations***

The AHTEG on Synthetic Biology, in its report (UNEP/CBD/SYNBIO/AHTEG/2015/1/3), also provided additional inputs on a way forward. It recommended, among other things, the establishment of a process to monitor and assess the state of knowledge within the field of synthetic biology on a regular basis, review new information regarding positive and negative impacts and update the proposed operational definition.

The AHTEG also urged Parties to address synthetic biology in a coordinated manner, particularly by tapping into existing processes, such as the AHTEGs on Risk Assessment and Risk Management, and on Socio-economic Considerations under the Cartagena Protocol. Coordination and synergies with other international organizations, the creation of online platforms and tools for sharing information, and the promotion of capacity building and encouragement of cooperation were also highlighted as important steps.

Notably, the AHTEG recommended that mechanisms for clarifying the issue of digital genetic resource information, as it relates to access and benefit-sharing, be set up under the Nagoya Protocol. The AHTEG also called for the assessment of

potential gaps in oversight under the Convention and its Protocols with regard to components and products of synthetic biology and the promotion of the full engagement of indigenous peoples and local communities.

Finally, it urged that discussion on the potential benefits and adverse effects of synthetic biology, the development of guidelines, public awareness, communication and education, and ethical considerations be promoted.

**Principles for a regulatory approach**

Based on the discussion in this chapter, the following are some principles that could apply in order to foster a holistic regulatory approach to synthetic biology (see also Friends of the Earth et al., 2012):

*General*

- There should be mandatory regulations applicable to synthetic biology, so as to minimize the potential adverse effects.
- Specific issues for consideration could include, for example, a ban on using synthetic biology to manipulate the human genome in any form, due to the ethical issues involved; a prohibition on development of agents for biological warfare (biosecurity considerations); and a moratorium on environmental and commercial release of organisms resulting from synthetic biology until procedures and regulatory processes or international regulatory frameworks are in place.
- The precautionary principle should apply to all aspects of synthetic biology.

*Risk assessment*

- In order to address the potential adverse effects of synthetic biology, risk assessment becomes necessary.
- This should be a pre-market case-specific assessment that considers direct, indirect, immediate and delayed impacts, and cumulative long-term effects.
- Risk assessment should also take into account risks to human health, and the need to protect public health and worker safety.
- Given that synthetic biology carries many scientific uncertainties, there should always be an acknowledgement of the gaps in scientific knowledge, potential unintentional effects and consideration of uncertainties, including making these known to decision makers.
- If any organism, product or component of synthetic biology is approved, this should be a time-bound approval and reassessment required in case of new information arising.

*Other regulatory considerations*

- It is critical that socio-economic considerations, including small-scale farming systems and their contribution to biological diversity and ecosystem function, food security and livelihoods, be taken into account.
- In particular, there must be consideration of indigenous peoples and local communities including cultural and ethical aspects.
- The fair and equitable sharing of benefits arising out of the utilization of genetic resources is also relevant for synthetic biology.
- Any potential damage caused by the organisms, components and products of synthetic biology should be addressed through a liability and redress regime.

- There should be post-market environmental monitoring in order to facilitate risk management and to identify and address any unintentional effects.
- This can be complemented by labelling and traceability measures and ensuring that there are robust detection methods available for the organisms, components and products of synthetic biology.

*Complementary issues*

- It is important that there is biosafety research to address the gaps in scientific knowledge and uncertainties, *a priori* to commercial release.
- As the technologies are developing rapidly, governments should conduct periodic reviews to ensure that regulations keep pace with technology developments and scientific knowledge.
- Throughout the process, transparency in research and regulation is needed.
- There should be provision of public access to all information regarding decision-making processes, safety testing and products, to ensure open, meaningful and full public participation.
- Governments should also fully consider alternative options to the synthetic biology organism, product or component in question, so as to enable informed decision-making.

## References

Eckerstorfer, M., Miklau, M. and Gaugitsch, H. (2014). *New plant breeding techniques and risks associated with their application.* Environment Agency Austria. http://www.ekah.admin.ch/fileadmin/ekah-dateien/New_Plant_Breeding_Techniques_UBA_Vienna_2014_2.pdf

Friends of the Earth, International Center for Technology Assessment and ETC Group (2012). *The principles for the oversight of synthetic biology*. http://www.etcgroup.org/content/principles-oversight-synthetic-biology

Report of the Ad Hoc Technical Expert Group on Synthetic Biology (2015). UNEP/CBD/SYNBIO/AHTEG/2015/1/3, 7 October 2015.

Secretariat of the Convention on Biological Diversity (2015). *Synthetic biology.* Montreal, Technical Series No. 82. https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf

Updated report and synthesis of views in response to paragraph 7(b) of Decision XII/24 on new and emerging issues: Synthetic biology. UNEP/CBD/SYNBIO/AHTEG/2015/1/2, 4 September 2015.

SYNTHETIC biology has been operationally defined as "a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems". The complexity and novelty of the technology present significant challenges in terms of its governance and regulation.

This booklet looks at the multilateral treaties that apply to various aspects of synthetic biology, including, most notably, the Convention on Biological Diversity and its Cartagena Protocol on Biosafety. Nevertheless, gaps still exist in the international legal framework when it comes to addressing all the potential negative impacts resulting from the application of synthetic biology techniques. In view of this, the author sets out several elements and principles that could underpin a more holistic regulatory approach towards this emerging new technology.

**Lim Li Ching** *has a B.Sc. in Ecology and an M.Phil. in Development Studies. She is a Researcher with the Third World Network and coordinates its biosafety programme. She is currently a member of the Ad Hoc Technical Expert Group on Socio-economic Considerations, established by Parties to the Cartagena Protocol on Biosafety.*

*Li Ching has been involved in the biosafety capacity-building programme of TWN and GenØk-Centre for Biosafety, Norway, and has been on the faculty of the international biosafety course Holistic Foundations for the Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms (2003-2012) and several other regional courses. She is co-editor of the book* Biosafety First, *published by Tapir Academic Press in 2007.*

**BIOTECHNOLOGY & BIOSAFETY SERIES**

is a series of papers published by the Third World Network. It is aimed at deepening public understanding of ecological and safety aspects of new biotechnologies, especially genetic engineering.

ISBN 978-967-0747-18-7

9 789670 747187