**Response to the Notification of the Secretariat regarding the Submission of information on Synthetic Biology [Ref: SCBD/SPS/DC/MPM/DA/86613]**

**(A) Research, cooperation and activities noted in the sub-paragraphs (a) through (c) above;**

In Brazil, activities developed based on the application of synthetic biology are regulated by the national Biosafety Law (Law n. 11.105/2005), which considers an organism developed by this technology a Genetically Modified Organism. This law follows a case-by-case approach, based on scientific evidence. The risk assessment analysis of GMOs is conducted according to the terms of Article 44 of Federal Decree n. 5.591/2005 and Normative Resolution n. 05/2008. It is worth noting that these regulations contain the methodologies established in Annex III of the Cartagena Protocol. Research activities include projects developed by public and private institutions, and all the requirements and biosafety measures are described in National Biosafety Technical Comission (CTNBio) Normative Resolutions No. 01/2006 and No. 02/2006.

It is important to emphasize that the process of risk assessments conducted in Brazil includes meetings with relevant sectors (civil society, academia, and private sector) and public consultations. The public and multi-stakeholder dialogues include bilateral meetings with different countries, the publication of all previous and final decisions about GMOs on the internet (http://ctnbio.mcti.gov.br/) and in official documents, public hearings about new events, open National Biosafety Technical Comission meetings (CTNBio) with public participation, government-industry dialogues about biotech themes, and government participation in different biotech forums.

**(B) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention;**

Organisms produced by nucleic acid synthesis, as well as GM organisms, are designed for a specific application, in such a way that they may contribute to a large variety of uses. Through the use of synthetic biology, scientists are able to design and build engineered biological systems that process information, manipulate chemicals, fabricate materials and structures (e.g., chemicals, proteins, enzymes, and fibers), produce energy (e.g., new fuels, biofuels, low-carbon fuels, energy security), provide food (e.g., plants and animals resistant to diseases and pests and/or adapted to different regions with high productivity), and maintain or enhance human health (e.g., pharmaceuticals, vaccines, hormones, diagnostic agents) and the environment (e.g., detection, treatment and pollutant degradation, bioremediation, biomining, reduction of greenhouse gas emissions, development of environmentally-friendly plastic, etc). It is important to mention that synthetic biology also can be used to address some of the main challenges facing society: climate change mitigation; energy security; water, soil and food security; improving the health of the world's poor and of ageing populations; and environmental protection.

It is not yet scientifically proven if risks that derive from synthetic biology are the same as risks presented by GMOs, and should therefore be approached by applying the correct risk hypothesis. The risks related with the three objectives of the Convention are:

-          Weediness, invasiveness and persistence

-          Gene flow

-          Soil function

-          Plant health

-          Biodiversity (potential impacts of transgenic plants on threatened species and threatened habitats)

In order to maximize potential benefits and avoid possible risks, the use of this technology should be based on a precautionary approach, with a science-based case-by-case risk assessment, as stated in Brazilian legislation and the Cartagena Protocol.

In accordance with Decision XIII/17 adopted by the 13th Conference of the Parties to the CBD, it is not possible to conclude whether all products deriving from Synthetic Biology techniques could be covered by the Cartagena Protocol.

In accordance with Decision XIII/24, which invited Parties and other Governments to take a precautionary approach and the principle of best available information, and due to the lack of scientific certainty about the possible environmental impacts of this technology, the Brazilian government suggests the following:

1. Synthetic biology should continue to be considered as a "new emerging issue", relevant to the achievement of CBD objectives, its thematic programs of work and cross-cutting issues, as it meets the criteria established by COP 9 Decision IX/29, and in view of possible new techniques that can be discovered;
2. The AHTEG of synthetic biology should be maintained for a continuous monitoring of new techniques or products of synthetic biology that require specific evaluations;
3. It is necessary to identify whether risk assessment carried out by the countries under the Cartagena Protocol is sufficient for the effective evaluation of living organisms obtained through the synthetic biology technique;
4. It is also necessary to identify if there are products and components created through synthetic biology that do not fall within the scope of Cartagena. If these exist, an international instrument should be chosen for the control of components and products (non-living) derived from synthetic biology;
5. Considering the potential for accidental release of products from new techniques, in view of the ease of access by non-trained citizens to new techniques, such as the purchase of kits containing "genetic parts", it is necessary to establish a Guide to good laboratory practices and characterization of the environment appropriate to the development of these new technologies;
6. Considering the cross-border potential of products derived from the new techniques, in particular gene drives, a risk assessment guide with minimum criteria should be established under Cartagena for living organisms and under the CBD for cases that do not fit under Cartagena;
7. The CBD and the Cartagena Protocol, according to their competencies, should adopt the procedures suggested by Oye 2014 for the release of organisms containing gene drives; and
8. The AHTEG of Socioeconomic Considerations of the Cartagena Protocol should analyze the impact of synthetic biology on productive chains of socio-biodiversity in face-to-face or online meetings.

**(C) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks**;

As aforementioned, in Brazil the national Biosafety Law (Law n. 11.105/2005) regulates activities related to research, development and the commercial release of Genetically Modified Organisms (GMOs), according to international guidelines (e.g. *Codex Alimentarius*, Cartagena Protocol on Biosafety).

It should be highlighted that the national Biosafety Law (Chapter I, article 3) defines recombinant DNA/RNA molecules as "the molecules manipulated outside living cells through the modification of segments of natural or synthetic DNA/RNA and which are capable of multiplying in a living cell, or even DNA/RNA molecules resulting from this multiplication; segments of synthetic DNA/RNA shall also be considered equivalent to natural DNA/RNA segments".

Therefore, activities and projects related to Synthetic Biology are regulated by the Biosafety Law in its Chapter I, Article 1: “*This Law provides for safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of genetically modified organisms – GMOs and their by-products, guided by the drive for attaining scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and the compliance with the principal of environmental precaution*.”

Although the aforementioned legal text clearly distinguishes between natural and synthetic nucleic acid molecules, its distinction is prescriptive to include those organisms that use synthetic material in the GMO category. Thus, GMOs may contain cloned or synthesized nucleic acids.

In addition, components or products derived from synthetic biology techniques are equally regulated in Brazil. However, since these components and products are chemically defined as pure substance, not containing GMOs, heterologous protein nor recombinant DNA, they are not regarded as GMOs in accordance with the Biosafety Law (Chapter I, Paragraph 2): "*The GMO derivative category shall not include a pure substance, chemically defined, obtained by means of biological processes and which does not contain a GMO, heterologous protein or recombinant DNA.*"

Therefore, these components and products do not differ from components and products obtained from organic or inorganic synthesis and are regulated in accordance with their use for a specific agency/Institute/Ministry, which already sets a wide range of regulations that must be complied with:

1. **ANVISA** (Brazilian Health Surveillance Agency) regulates products intended for human use and health;
2. **IBAMA** (Brazilian Institute for the Environment and Renewable Natural Resources) regulates products intended for use in the environment;
3. **MAPA** (Ministry of Agriculture, Livestock and Food Supply) regulates products intended for use in agriculture.

**(D) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology;**

In Brazil, the principles guiding risk assessment analysis under the Brazilian regulation include: (i) a science-based approach; (ii) a case-by-case assessment; and (iii) a comparative analysis, according to international principles and guidelines adopted by other countries. There is also a monitoring system that includes inspection measures conducted by official inspectors in the research and commercial activities with GMOs and a post-release monitoring plan approved by the competent authority and implemented by the applicant.

The only example of an organism that could be considered a Synthetic Biology organism approved in Brazil is genetically modified yeast (strain Y1979 and Y5056 - Technical Reports n. 2281/2010 and n. 3287/2012, respectively). Those are GM organisms under contained use and there are specific requirements and rules regarding these organisms according to the CTNBio Normative Resolution n. 01/2006 and n. 02/2006. These organisms are used to produce biofuels.

**(E) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology;**

The Cartagena Protocol defines 'LMOs' as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*";* whereas *"*modern biotechnology" is defined as: "the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (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”.

In Brazil, the Normative Resolutions that are used for the risk assessment of GMOs are also used in the case of SynBio organisms, without any additional requirement.

Based on the text of the Protocol, one can say that:

1. The legal requirement to define a LMO is the presence of genetic modification;

2. Modern biotechnology is based on nucleic acids modification, including DNA, therefore, the technique also includes the use of RNA;

3. The nucleic acids direct introduction (DNA/RNA) in cells or organelles is also covered by the text;

4. The definition considers LMOs that are able to replicate or transfer genetic material including viruses and viroids.

For these reasons, in most cases, a LMO derived from Synthetic Biology is not different from a LMO derived from rDNA techniques. The possible differences between a LMO and an organism produced through the application of synthetic biology lies mainly on its complexity. Such complexity may be a result of the combination of several techniques of genetic engineering to produce an organism.

Therefore, the central question remains on assessing whether the new organism may present a risk to the conservation and sustainable use of biodiversity, independently if this organism is engineered using rDNA or Synthetic Biology techniques.

In Brazil, the same Normative Resolutions that are used for GMO risk assessments are used in the case of Synthetic Biology organisms without any additional requirement: CTNBio Normative Resolution n. 01/2006 (requirements for activities with GMOs), CTNBio Normative Resolution n. 02/2006 (requirements for contained use), CTNBio Normative Resolution n. 05/2008 (requirements for commercial release). These Resolutions are under continuous review by the National Biosafety Technical Comission, according to scientific advances and technical requirements.

**(F) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology.**

As mentioned in item (B), it is not yet scientifically proven that the potential adverse effects of organisms resulting from synthetic biology are the same as risks presented by GMOs. In Brazil, the cultivation of genetically modified organisms is forbidden in indigenous lands. The potential benefits of this technology are mainly focused on the conservation of endangered species, including the possibility of genomic reconstruction of extinct species.

It is also important to highlight that Brazil also has a law entitled "Access and Benefit Sharing Law" (Law n. 1.123/2015), which addresses access to genetic resources, protection and access to associated traditional knowledge and benefit sharing for the conservation and sustainable use of the Brazilian biodiversity. This legislation makes evident another potential benefit of Synthetic Biology for indigenous and local communities, since the domestic ABS Law sets forth the basis for benefit sharing resulting from economic use of a finished product or reproductive material resulting from access of national genetic heritage or associated traditional knowledge.

The development of Synthetic Biology technologies and the application of access and benefit sharing regulations could prompt the use of genetic resources and/or traditional knowledge in ways that indigenous people could benefit from the development and future deployment of new technologies and products.

As aforementioned, the AHTEG on Socioeconomic Considerations of the Cartagena Protocol should analyze the impact of synthetic biology on productive chains of socio-biodiversity in face-to-face or online meetings. Parties should follow a precautionary approach, bearing in mind that it requires experience, information sharing, risk assessment and practical cases as the basis to deal with any new technology.