**INFORMATION ON SYNTHETIC BIOLOGY**

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

Synthetic biology is a new and emerging field within modern biotechnology that through engineering and de novo synthesis of genetic material. Synthetic Biology aims to design new biological systems that do not yet exist in nature, for human, agricultural and environmental purposes. The areas of research that are considered “synthetic biology” include DNA-based circuits, synthetic metabolic pathway engineering, synthetic genomics, protocell construction, and xenobiology.

To date, despite the activities carried out in some laboratories using molecular biology techniques for the diagnosis, characterization of certain microbial strains and plant germplasm, etc., the DRC does not yet have the required capacities to carry out Research on Synthetic biology. Nevertheless, some laboratories use certain techniques of biotechnology, in particular genetic engineering using *Agrobacterium rhizogenes* to produce hairy root and improve the production of secondary metabolites with high biological activity with a view to develop drugs. Others also use Biotechnology techniques to develop crops that are tolerant to abiotic and biotic stresses, produce Biofuels, for environmental monitoring, etc.

However, within the framework of regional cooperation at Southern African region, some scientists and other stakeholders of the Convention participated in the SADC trainings and workshop on synthetic biology.

b) **Evidence of benefits and adverse effects of synthetic biology** vis-à-vis the three objectives of the Convention.

In DRC, research has not yet been undertaken to this end. The risks that synthetic organisms pose to the environment are not yet well understood. However, according to CBD (2015) , components, organisms and products of synthetic biology may have some **positive impacts** on the conservation and sustainable use of biodiversity. Many of the applications of synthetic biology aim at developing more efficient and effective ways to respond to challenges associated with bioenergy, environment, wildlife, agriculture, health and chemical production. For example:

- The development of micro-organisms designed for bioremediation and biosensors resulting in pollution control and remediation of environmental media;

- Synthesizing products such as chemicals or drug precursors that are currently extracted from plant or animal sources, thereby reducing the pressure on wild species that are currently threatened due to over harvesting or hunting;

- Developing organisms designed to generate biofuels which may lead to decreased dependence on non-renewable energy sources;

- Capability, in the field of production of crops tolerant to abiotic stress and pests, to further refine expression and environmental persistence of the products in the organism;  Restoring genetic diversity through reintroducing extinct alleles, or even “de-extinction” of species.

Organisms and products of synthetic biology could also have some **negative impacts** on the conservation and sustainable use of biodiversity including, for example:

- Adverse effects of microbes intended for release into the environment due to their potential for survival, persistence and transfer of genetic material to other microorganisms;

- Potential undesired consequences could result from the use of “gene drive” systems to spread traits aimed at the suppression or extirpation of populations of disease vectors (e.g. mosquitoes):

* Case of the introduction of new diseases through the replacement of the population of the original disease vector by another vector species (“niche substitution”);

- Possible toxic and other negative effects on nontarget organisms such as soil micro-organisms, beneficial insects, other animals and plants;

- Potential negative impacts to the conservation and sustainable use of biodiversity could arise from:

* the transfer of genetic material to wild populations via vertical gene transfer and introgression.
* a large-scale increase in the utilization of biomass. Much of the synthetic biology research being focused on designing organisms that will use biomass as feedstock to produce fuels, chemicals, and pharmaceuticals, some applications (e.g. fuel production) would require high amounts of biomass, which could lead to a rapid decline in soil fertility and structure, and contribute to biodiversity loss and climate change through direct and indirect land-use change.

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**.

Risk assessment of organisms, components and products of synthetic biological is complex. This is due to the fact that these organisms, components and products do not have the potential comparators in nature. Due to the complexity and novelty of the organisms developed through synthetic biology, the type and depth of information that may be required to assess their risks will differ from the information typically provided by developers for conducting risk assessments of LMOs. For the CBD (2015), existing biosafety risk assessment frameworks are likely to be sufficient to assess the risks of current and near-term applications of synthetic biology on the conservation and sustainable use of biodiversity. The general risk assessment methodology for living modified organisms is expected to be applicable to organisms produced through synthetic biology. However, synthetic biology develops. This assessment may need to be revisited. Specific consideration will likely be needed to identify any gaps that exist in the risk assessment methodologies that are currently in place for living modified organisms and propose guidance on how to fill such gaps. Odd-Gunnar of GenØk suggested that the case-by-case and step-by-step approach recommended in risk assessment of GMOs is highly relevant to synthetic organisms and there for, much of the current unanswered question are not connected to specific products, but to general observations of the individual approaches to synthetic biology. For Sarah Agapito, always from GenØk, there is a need to continue to revise and further develop risk assessment methodologies in order to fully address the potential environmental and societal impacts of future synthetic biology applications. The approach of whole organisms analysis using untargeted “omics” techniques (genomics, transcriptomics, proteomics and metabolomics) has been pointed as one possible element of a way forward. “Omics” technologies or molecular profiling are considered as an important way to increase confidence in risk assessments for any GMOs but also to new synthetic biology organisms and products.

Specific challenges with regard to risk assessment principles currently applied are the future developments in synthetic biology. As such, there may 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.

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**.

To mitigate potentials risks for human health and environment, management measures to apply for any activities involving the use of synthetic biology are the use of biological confinement and the physical containment that prevent the release of organisms resulting from synthetic biology techniques into the biosphere. This depending on the risk that could arise organisms, components and products of synthetic biology. If the risks cannot be properly assessed due to scientific uncertainties, the activities involving such organisms should be assigned to a sufficiently high level of containment.

e) **Regulations**, **policies** and **guidelines in place** or under development which are directly relevant to synthetic biology.

A specific regulation for synthetic biology does not yet exist in DRC. In the meantime, some existing national and international regulations are being used; especially :

- The precautionary principle as the basis for evaluating the applicability of life science innovations.

- At national level: Legislation on trade (Law No. 73-009 of 5 January 1973), General legislation on environmental protection (Law No. 11/009 09 July 2011), Biodiversity legislation (Law No. 011-2002 of 29 August 2002 , Law No. 14/003 of 11 February 2014), Food and food hygiene legislation (Decree of 26 July 1910 , Ordinance of 17 October 1911, Ordinance No. 74-453 of 31 December 1952 , Ordinance No. 41-412 of 7 December 1953 ), Legal framework of agriculture and livestock (Law No. 11/022 of 24 December 2011 ).

- At international level: Cartagena Protocol on Biosafety (Transfer of genes, Effects on ecosystem and other species); Convention on Biological Diversity, Cartagena Protocol on Biosafety (Effect on biodiversity).

In the meantime of a harmonization among countries, Self regulation approach proposed by the industry sector for synthetic biology companies and biohackers, especially the adoption of code of conduct by scientists, may be seen as important steps to reinforce global security.

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.

Following a lack of communication among the regulatory bodies involved in research and biosafety, the majority of congolese population is not yet informed about synthetic biology. But like GMOs, it will arise at the level of indigenous peoples the acceptance problem of synthetic biology and ethical questions. Indigenous peoples live with natural resources. Synthetic biology applications to plants in the field with undeliberate and unknown effects will constitute a threat to biodiversity.

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