Mr. Braulio Ferreira de Souza Dias
Executive Secretary
Convention on Biological Diversity
Montreal, Canada

GenØk - Centre for Biosafety
Siva innovasjonssenter
PB. 6418,
9294 Tromsø, Norway

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Dear Madam/Sir,

GenØk - Centre for Biosafety in Norway is pleased to submit its peer-revision to the reports UNEP/CBD/SYNBIO/AHTEG/2015/1/3 and UNEP/CBD/SYNBIO/AHTEG/ 2015/1/2 for consideration by SBSTTA at its twentieth meeting to be held in Montreal, Canada from 25 to 29 April 2016.

Thank you for your kind consideration.

Respectfully yours,

Anne Ingeborg Myhr
Director of GenØk

GenØk – Centre for Biosafety
Adr.: Siva innovasjonssenter, Pb. 6418, 9294 Tromsø, Norway
Tel. +47 77 64 66 20
www.genok.com post@genok.no

GenØk Submission on Documents

- **UNEP/CBD/SYNBIO/AHTEG/2015/1/3 7 October 2015**
- **UNEP/CBD/SYNBIO/AHTEG/2015/1/2 4 September 2015**

GenØk Center for Biosafety would like to recall that the objectives of the Convention on Biological Diversity is to pursue *in accordance with its relevant provisions, the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding*.

GenØk also notes that according to the definition of 'biological diversity' as per the Convention - *"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.* - organisms, components and products of synthetic biology techniques cannot be understood as potential biodiversity. This is because organisms, components and products of synthetic biology techniques are not part of any existing natural ecosystem. Therefore, GenØk understands that discussions on potential benefits of such products to biodiversity, as provided in section 3.5 of document UNEP/CBD/SYNBIO/AHTEG/2015/1/3 and section V of document UNEP/CBD/SYNBIO/AHTEG/2015/1/2, are inappropriate due to their speculative matter and because their arguments are not based on current scientific knowledge. Further comments on each section from both documents are provided below.

a) Information on peer review of the outcomes of the process in response to decision XII/24 on synthetic biology

i. Towards an operational definition of synthetic biology comprising inclusion and exclusion criteria

.Recalling the need for understanding that the definition here is in the context of the Convention and also to assist in the implementation of the Convention's provisions, GenØk would like to note that a definition in this case should be effective and operational in the regulatory sphere, should also seek to encompass the present and foreseeable aspects of synthetic biology, which then might not accommodate scientific definitions of such a term.

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Therefore, GenØk perceives the proposed definition contained in page 4 of document UNEP/CBD/SYNBIO/AHTEG/2015/1/3, while useful, as remaining too vague as to be operational. On one hand it is relevant to foreseen future products of synthetic biology but at the same time, it brings a duality to its interpretation. GenØk understands that the current definition should also be corrected, if accepted, as follows:

"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 ***OR*** *biological systems."*

This change would better suit components and products of synthetic biology, which do fall within the scope of this Convention. If not corrected, there is the danger that the definition could be misinterpreted to mean that only products additively matching the three criteria, being genetic materials AND living organisms AND biological systems would be defined as synthetic biology.

Our suggestion is in agreement with the Convention definition of 'biotechnology' on Article 2, Use of Terms:

"Biotechnology" means any technological application that uses biological systems, living organisms, ***OR*** *derivatives thereof, to make or modify…*

ii. Relationship between synthetic biology and biological diversity

GenØk agrees with the urgent need for appropriate baselines for measuring the potential impacts of synthetic biology on each of the objectives of the Convention and that these urgently need to be considered and developed supported by evidence-based information, including peer-reviewed data, as well as specialized knowledge, indigenous and traditional knowledge.

GenØk understands as being highly difficult, if not speculative, to foresee any positive impact of synthetic biology products from an ecosystem's perspective. GenØk's long history of research in the field of gene ecology has showed that the release of non-natural products in natural ecosystems will cause disturbance to its natural course and evolution. Therefore, organisms and products produced by synthetic biology are highly unlikely to have a positive impact on the ecosystem.

GenØk calls attention to statements that relate synthetic biology techniques to being more predictable in the characteristics of the resulting organisms. GenØk's recent report on

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emerging plant breeding technologies[1], which include several synthetic biology techniques as defined by the suggested definition, shows that the current scientific knowledge cannot support this statement. At this stage, there is potential for synthetic biology to be more precise as a genetic engineering tool, however, the efficiency and off-target effects of synthetic biology techniques are not yet understood. In addition there is a significant scientific debate as to the mode of action of natural biological pathways utilized the process of developing synthetic biology organisms.

Nonetheless, GenØk also agrees that regulators and decision makers will face challenges in fully addressing impacts of synthetic biology. Therefore, GenØk would like to recall that the precautionary approach should be taken by Parties. Also, GenØk recognizes that the Convention objective of fair and equitable sharing of the benefits arising out of the utilization of genetic resources may indeed be challenged as use of components, organisms and products from synthetic biology may change manners of access and use of natural genetic resources. It would be therefore important to also recognize and address the potential for misappropriation in the generation and use of digital information on genetic resources.

iii. Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques

Although non-living components and products of synthetic biology might have limited coverage under the scope of the Cartagena Protocol on Biosafety, GenØk would like to call attention to the fact that many national regulations might include those under their own biosafety laws. In addition, many developing countries may have to follow and implement those regulations without relevant issues being addressed under the Cartagena Protocol. In GenØks opinion, non-living components and products of synthetic biology must be specifically addressed under the Convention, and any discussions of products and components must be included in the coordination of discussions on synthetic biology living organisms, including the discussions with the other AHTEGs under the Cartagena Protocol.

iv. Adequacy of other existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques

GenØk recognizes that the Cartagena Protocol has a greater experience in developing risk

[1] Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis. Agapito-Tenfen, S.Z. og Wikmark, O.-G. 2015 GenØk Biosafety Report 02/15, 43p. Available at: http://genok.no/wp-content/uploads/2015/06/250615_Emerging_technologies_final.pdf

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assessment of biotechnological products, as well as other technical developments such as the network of detection and identification of living modified organisms, than the Convention. Therefore, GenØk would like to suggest adjustments of the Cartagena Protocol activities and resources to assist the Convention in this matter.

GenØk highly recommends a special task force to be organized to address issues related to traceability and detection tools not only to ensure fair and equitable sharing of benefits arising from the utilization of synthetic biology products but also to ensure detection and identification of such organisms in the environment for monitoring, risk assessment and labeling provisions. GenØk anticipates that some of these products might be indistinguishable with current detection techniques and that there is an urgent need to Parties to consider that for synthetic biology products.

v. 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 socioeconomic impacts relevant to the mandate of the Convention and its Protocols

GenØk disagrees with statements that point to similar impacts of synthetic biology and genetic engineering products. In fact, statements in point 44 of page 7 of document UNEP/CBD/SYNBIO/AHTEG/2015/1/3 are conflicting.

GenØk understands that point 45 is one of the most important issues to be discussed in regards to potential threats of synthetic biology products to biodiversity. GenØk agrees that in comparison with classical genetic engineering, a distinctive quality of synthetic biology is its rate and depth of intervention, which will lead to decreased familiarity of the organisms developed through synthetic biology in comparison with non-modified organisms. However, The level of uncertainty in risk assessment may increase with regard to the impacts on biodiversity and human health as well as the increased pressure to reduce time needed to complete the risk assessments. GenØk would therefore reinforce the importance of a precautionary approach.

GenØk understands as being inappropriate to speculate on potential positive impacts of synthetic biology products and already would like to address some questions regarding the examples presented in page 8 of document UNEP/CBD/SYNBIO/AHTEG/2015/1/3:

- Bioremediation may contribute to the restoration of ecosystems from only a human perspective. Nonetheless, as *per* the Convention definition, biological diversity should be perceived as those present in natural existing ecosystems. In those cases, the introduction of synthetic biology products might, on the contrary, provoke more disturbances to the ecosystem's natural capacity of restoration and resilience.
- Resistance or tolerance to various stress, such as diseases and abiotic stresses will be

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most likely introduced with proprietary components. When those products are released into the environment they will actually have the potential to threaten existing biological diversity by replacement. Not only that but the introduction of any biotechnological material by itself cannot be considered biodiversity and therefore cannot contribute to species conservation.

vi. Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments

GenØk would like to emphasize the need for best practices on the standardization of risk assessment methodologies and on monitoring on synthetic biology. It is relevant to mention that such practices have been debated within the Cartagena Protocol for assessing the impacts of living modified organisms. Unfortunately, September 2015 marks the 12th anniversary of the entry into force of the Cartagena Protocol on Biosafety and so far no standardized guidance document on risk assessment has been endorsed or adopted by Parties. And this is despite the fact that a comprehensive and robust guidance document has been produced by a large group of expert scientists, AHTEG groups, and peer reviewed processes since 2008. This reflects the difficulty of such processes but also the disagreements between Parties on that matter. GenØk would like to urge Parties to decide for a more effective process for the development of synthetic biology products risk assessment before it is too late to implement the Convention's objectives.

vii. Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity

GenØk recalls one of the most important issues in this document, which is related to the lack of appropriate comparator for the risk assessment of synthetic biology products. GenØk emphasizes that current risk assessment approaches and methodologies must be urgently adapted to address matters that are of particular relevance to synthetic biology.

The particular matter of synthetic biology is related to the lack of familiarity in comparison with non-modified organisms, challenges in establishing meaningful comparators, and possibly higher levels of uncertainty, as there are gaps in the existing methodologies for assessing the environmental impacts of organisms of synthetic biology. There is therefore identified a need for guidelines and capacity-building to be developed and made available. This is of major importance considering that most, if not all, existing risk assessments frameworks are based on a comparative assessment. The lack of an appropriate comparator invalids the capacity of any existing risk assessment procedures to effectively assess potential

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threats to biodiversity. GenØk calls attention to the interactions among the new genetic parts in synthetic biology products that will have no comparable counterpart in nature, making it more difficult to predict an organism's full behavioral range with a high degree of certainty. Therefore, GenØk understands that the current existing frameworks do not constitute a comprehensive framework to address the impacts of synthetic biology products.

Finally, GenØk would like to recommend to Parties to urge the Open-ended Online Expert Forum (Online Forum) on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to work specifically on the development of a new comprehensive framework in order to address the impacts of organisms, components and products resulting from synthetic biology.

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