

*Annex*

**TEMPLATE FOR COMMENTS ON THE REPORT OF THE AD HOC  
TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY**

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<b>Comments on the draft documentation for SBSTTA-21:</b>		
<b>Page #</b>	<b>Para #</b>	<b>Comment</b>
3	16, 17	<p>It would be relevant to refer to the precautionary approach in these two paragraphs, given the challenges posed by synthetic biology to risk assessment and on the ability to understand the possible impacts on biodiversity and human health.</p> <p>The precautionary approach is in conformity with the Convention on Biological Diversity (CBD) and its Protocols (Cartagena Protocol on Biosafety, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress). Numerous decisions of the Conference of Parties to the CBD in relation to synthetic biology have also been adopted that call for a precautionary approach, the latest being Decision XIII/17.</p>

3	18	<p>While well-designed strategies are needed to prevent exposure of organisms, components and products of synthetic biology under contained use to the environment, we are of the view that stringent regulations are also necessary. Where there are gaps in regulation, these should be urgently addressed.</p> <p>For example, to our knowledge, there are no internationally agreed contained use regulations that specifically address organisms containing engineered gene drives. It is our view that strict containment rules are necessary for such organisms, given the potential for spread and adverse effects on the conservation and sustainable use of biological diversity, should breaches in containment occur.</p> <p>With the novel capabilities of synthetic biology, and their potentially increased impacts on biodiversity, a new assessment of risks stemming from contained use is also merited. Experiments such as synthetic biology gain of function studies with animal pathogens have potentially great impacts on biological diversity and human health, and a series of recent incidents at high containment laboratories, including repeated accidental releases by labs regarded as being highly professional and secure, draw attention to the inevitability of containment failure.</p> <p>Other applications described as contained use, for example, large-scale synthetic biology biofuels production, can involve cultures of tens of thousands of liters of organisms and can carry greater risks than envisaged.</p> <p>Therefore, synthetic biology applications in contained use present novel risks upon unintentional release and this also needs to be properly assessed and regulated by the Convention and its Protocols, as appropriate.</p>
4	20	<p>We agree that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology is useful, if not crucial, given the fast-paced developments. Furthermore, a formal mechanism should be set up by which this can be done, and the outcomes reported regularly to Parties via SBSTTA, the COP and COPMOPs, as appropriate. This is to ensure that there is an established process by which Parties can take decisions in response to these developments.</p> <p>Since the issue of synthetic biology is relevant to several areas of the Convention and its Protocols, it must also be ensured that how synthetic biology is addressed is not just divided into constituent pieces at the expense of an oversight of the whole. Parties therefore need to use and maintain this oversight process to conduct stock-taking and adopt cross-cutting decisions.</p>

4	25	<p>Given the potential significant and irreversible adverse effects to biodiversity of organisms containing engineered gene drives, including the potential for unintended transboundary movements and geographic spread of organisms released into the environment, we agree fully with the sentiments of this paragraph.</p> <p>In addition, and in accordance with the precautionary approach, we urge Parties to ensure that organisms containing engineered gene drives are not developed or released, including for experimental releases, until which time there are internationally agreed methods and rules for effective containment, assessment (including of socio-economic impacts), detection, monitoring and management of such organisms.</p> <p>Furthermore, in accordance with the UN Declaration on the Rights of Indigenous Peoples, the free, prior and informed consent of indigenous peoples and local communities is a prerequisite in the case of proposed releases into lands and territories of indigenous peoples and local communities.</p>
5	26	<p>In order to be able to fully consider the possible impacts of synthetic biology on the traditional knowledge, innovation, and practices of indigenous peoples and local communities, this issue should be placed on the agenda of the Working Group on Article 8j.</p> <p>Specific mechanisms and processes also need to be put into place under the Convention and its Protocols to ensure the meaningful participation of indigenous and local communities in the discussions and decision-making on synthetic biology. Article 23 of the Cartagena Protocol would also need to be implemented effectively.</p>
6	35	<p>Traceability and documentation for identity preservation are useful tools and may be particularly useful for the identification and monitoring of organisms developed through synthetic biology that do not have a suitable marker.</p>
6	36	<p>We agree with this paragraph tasking the Network of Laboratories for the Detection and Identification of LMOs, established under the Cartagena Protocol on Biosafety, to play an expanded role in relation to the detection, identification and monitoring of the organisms, components and products of synthetic biology.</p>
6	38	<p>Developers of organisms resulting from synthetic biology should be made responsible for providing validated tools, relevant sequence data and reference materials, in an accessible manner, by inclusion of such responsibilities in the relevant national legislation. In addition, where these are already required to be made available, the information should be shared via relevant databases such as the Biosafety Clearing House.</p>
6,7	41	<p>We agree that updates and adaptations to risk assessment methodologies might be needed to account for the situations spelt out in this paragraph. In addition, the specific considerations highlighted in the outline developed by the previous AHTEG on Risk Assessment and Risk Management under the Cartagena Protocol are also relevant (as contained in UNEP/CBD/BS/COP-MOP/8/8/ADD3: Outline of Guidance on Risk Assessment of Living Modified Organisms Developed through Synthetic Biology). These specific considerations should be integrated into any further work on risk assessment of LMOs developed through synthetic biology that may be carried out under the Convention and its Protocols.</p>

7	42	The Guidance on Risk Assessment of LMOs and Monitoring in the Context of Risk Assessment should be specifically mentioned in this paragraph, given its utility and relevance to Parties to the Cartagena Protocol on Biosafety.
7	43	The rights recognized by the United Nations Declaration on the Rights of Indigenous Peoples should be taken into account, not just in the assessment of the potential impacts of synthetic biology, but also in all respects and in the exercise of decisions that affect indigenous peoples and local communities.
7	44	<p>We agree that the risks that might arise from organisms containing engineered gene drives would provide challenges for risk assessment, and that the development or further development of guidelines on risk assessment of organisms containing engineered gene drives is necessary. This work should be prioritized by the Convention and its Protocols, to ensure that there is development and use of guidelines that are in line with their objectives and mandates, which may not necessarily be the case with guidelines developed through other processes or fora.</p> <p>The considerations highlighted in the outline developed by the previous AHTEG on Risk Assessment and Risk Management under the Cartagena Protocol in relation to engineered gene drives are also relevant (as contained in UNEP/CBD/BS/COP-MOP/8/8/ADD3: Outline of Guidance on Risk Assessment of Living Modified Organisms Developed through Synthetic Biology) and should be integrated into any further work on risk assessment of LMOs developed through synthetic biology, including for organisms containing engineered gene drives, that may be carried out under the Convention and its Protocols.</p>
7	45	We are of the opinion that the step of release of organisms containing engineered gene drives into the environment might be irreversible and, therefore, a precautionary approach is urgently warranted. We urge Parties to ensure that organisms containing engineered gene drives are not developed or released, including for experimental releases, until which time there are internationally agreed methods and rules for effective containment, assessment (including of socio-economic impacts), detection, monitoring and management of such organisms.
7	48	Strategies for risk management and monitoring of LMOs should be adapted and complemented in order to address specific characteristics of organisms developed through synthetic biology. Useful information on monitoring is contained in the Guidance on Risk Assessment of LMOs and Monitoring in the Context of Risk Assessment developed under the Cartagena Protocol on Biosafety. It is important that both case-specific monitoring and general surveillance are implemented to monitor the organisms, components and products of synthetic biology.

8	51	<p>To our knowledge, there are no internationally agreed contained use regulations that specifically address organisms with engineered gene drives. It is our view that strict containment rules are necessary for such organisms, given the potential for spread and adverse effects on the conservation and sustainable use of biological diversity, should breaches in containment occur.</p> <p>Release of organisms with engineered gene drives into island environments is a release into the environment, and our view is that Parties need to ensure that organisms containing engineered gene drives are not developed or released, including for experimental releases, until such time there are internationally agreed methods and rules for effective containment, assessment (including of socio-economic impacts), detection, monitoring and management of such organisms.</p>
8	52	<p>We agree that regular horizon scanning to keep track of progress in the adaptation of risk assessment and risk management of organisms developed through synthetic biology is useful. Furthermore, a mechanism should be set up by which such horizon scanning can be done, and the outcomes reported regularly to Parties via SBSTTA, the COP and COPMOPs, as appropriate. This is to ensure that there is a process by which Parties can take decisions in response to these developments.</p>
8	53	<p>We agree with the need to take into account the socio-economic impacts, perspectives, rights and lands of indigenous peoples and local communities when considering the possible release of organisms developed through synthetic biology into the lands and territories of indigenous peoples and local communities.</p> <p>Furthermore, in accordance with the UN Declaration on the Rights of Indigenous Peoples, the free, prior and informed consent of indigenous peoples and local communities is a prerequisite in the case of proposed releases into lands and territories of indigenous peoples and local communities.</p>