Annex

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

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Comments on the draft documentation for SBSTTA-21:		
Page #	**Para #**	**Comment**
0	0	General comments: • The report lacks balance in that it fails to adequately explain the – sometimes unique - potential benefits of Synthetic Biology (SB) for the conservation and sustainable use of biodiversity. In addition, SB has the potential to drastically reduce the number of animals for testing and production as well as address major threats of biological diversity loss. • The report contributes to the misperception that the use of NBTs and the development of gene drives per se constitute Synthetic Biology (SB). SB is not any particular technique but rather an overall approach based on design. • The report conveys an unsubstantiated notion of SB being uncontrollably dangerous (e.g. using terms as “accelerated rate”, “ever increasing speed of developments”, and “irreversible”). The report fails to explain that – in any case for the foreseeable future - organisms developed through SB fall under existing biosafety regulations. The standard step-by-step approach in combination with the case by case notification/authorisation systems and the and risk assessment methodology outlined in the CPB provide adequate safeguards. PRRI hopes that the SBSTTA will address these points in its recommendations to the COPMOP.
3	15(f)	This paragraph should recognise that – in any case for the foreseeable future - organisms developed through SB fall under existing biosafety regulations. The standard step-by-step approach in combination with the case by case notification/authorisation systems and the and risk assessment methodology outlined in the CPB provide adequate safeguards.

3	16	Same comment as 15(f). In addition: it should be underlined that it will be very helpful that authorities share their experiences with this through the CPB-BCH.
3	17	The suggestion that for gene drives we should assess "more thoroughly" the effects at the ecosystem level conveys a peculiar notion, as if in other cases it is fine to do that in a wishy-washy manner. Whenever we conduct a risk assessment, we should do that thoroughly in accordance with Annex III of the CPB, not only in some cases.
3	18	The report should have made clear that applying appropriate containment strategies is a standard element of biosafety and not something specific for synthetic biology.
3	19	Dual use and biosecurity are terms typically used in the context of Chemical and Biological Weapons, and mixing it in a discussion under the CBD is confusing.
3	20	The report should avoid phrasing as 'negative impacts of synthetic biology', and instead use the phrasing used elsewhere 'organisms developed through synthetic biology.
	21	International collaboration to allow all stakeholders to stay abreast of the developments is very welcome.
	25	Gene drives per se constitute Synthetic Biology (SB). The report should explain that – in any case for the foreseeable future - organisms developed through SB fall under existing biosafety regulations. The standard step-by-step approach in combination with the case by case notification/authorisation systems and the and risk assessment methodology outlined in the CPB provide adequate safeguards.
	33	The phrase "the resulting LMO is indistinguishable from the naturally occurring… detection, monitoring tools might be needed" raises the question why this would be needed if an organism cannot be distinguished from a naturally occurring one or a conventionally bred counterpart. If the resulting organism in indistinguishable from the naturally occurring, it cannot be more of a threat to biodiversity than the natural one.
	35	We see no reasons for the - unsubstantiated – suggestion by the AHTEG that existing identification methods would need to be updated and adapted for organisms produced by synthetic biology.
	41	For current and near future applications the existing case-by-case RA&RM is adequate. In addition, it should be noted that risk assessment methods advance in parallel with molecular biology advances. In the future, if organisms that differ more fundamentally from naturally occurring ones are developed, containment should be applied on a case-by case and in a risk-proportionate manner to progressively obtain the data to make the RA&M measures. Moreover, none of the issues listed in paragraph 41 are specific to SB.
	43	It is not helpful to introduce concepts that are not addressed in the CPB itself.

	45	The standard step-by-step approach in combination with the case by case notification/authorisation systems and the and risk assessment methodology outlined in the CPB provide adequate safeguards.

1. Completed forms can be sent to Secretariat via e-mail at synbio@cbd.int or submitted online at http://bch.cbd.int/managementcentre/edit/submission.shtml
2. Additional rows can be added to this table by selecting “Table” followed by “insert” and “rows below”