TEMPLATE FOR COMMENTS AND ADDITIONAL VIEWS ON DRAFT DOCUMENTATION ON SYNTHETIC BIOLOGY

Contact information	
Surname:	Didier
Given Name:	Breyer
Government	Belgium
(if applicable):	
Organization:	Scientific Institute of Public Health – Biosafety and Biotechnology Unit
Email:	didier.breyer@wiv-isp.be
Document reviewed	New and emerging issues relating to the conservation and sustainable use of biodiversity - synthetic biology: Possible gaps and overlaps with the applicable provisions of the Convention and its Protocols

Comments on the draft documentation on new and emerging issues – deadline 20 September 2013		
Page	**Line**	**Comment**
3	42	Various types of research of synthetic biology (SB) are mentioned. Why approaches in SB such as "genome minimization" and "synthetic genomics" were not considered? Note that on page 6 line 12 "genome-driving cell engineering" has been mentioned (of which we think it encompasses "synthetic genomics").
4	1-28	Same comment as above.
5	51	It should be noted that the term "living" has been defined by the CPB and that this definition might be also valid for the CBD.
6	24-27	It should be stressed that determining whether a LMO resulting from biotechnology is likely to have adverse environmental impact can only be done as a result of an environmental risk/impact assessment. There are well-defined and internationally recognized procedures and criteria for the environmental risk assessment of potentially hazardous products (including LMOs) which also include the fact that insufficient knowledge might be available (which in general will lead to the adoption of more stringent management measures). This whole section should also be nuanced by specifying in the text that the environmental risk assessment is a case-by-case process, depending on the organism concerned, its intended use and the likely potential receiving environment.
6	29-42	Whether the potential dangers related to SB are known or can be assessed will also much depend on the state of development. We think it is also worth to mention that current developments in SB mainly involve the use of well-characterized micro-organisms and genetic material, for which sufficient knowledge and appropriate comparators are available to assess the potential risks.
6	39-42	We agree that some developments in the field of SB could lead to environmental applications in case organisms are deliberately released into the environment. Addressing potential environmental risks in case of deliberate release adds a layer of complexity to the risk assessment as one has to deal with the complexity of biological and physico-chemical interactions. For applications involving micro-organisms it should be noted that risk assessors and regulators have relatively little experience considering the potential risks posed by the intentional release of micro-organisms, and that this applies to all LMOs, whether or not they have been produced by SB. Indeed the experience gained in the environmental risk assessment of LMOs comes almost exclusively from GM plants.

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		Compared to environmental plant biology the environmental microbiology is more complex and there is still little knowledge about the natural baseline of soil functioning (the nature of the soil microbiota, its dynamics, activities, interactions and response upon a disturbance), a key element to perform an environmental risk assessment. Keeping this in mind, we are of the opinion that addressing potential challenges in environmental risk assessment is premature since environmental applications of SB are not expected to materialize before several years.
11	36-43	While we understand the rationale of discussing terms separately, it should be stressed that all terms in the LMO definition are intrinsically interlinked. For instance, the novelty of a combination of genetic material can be considered only when modern biotechnology has been applied, meaning that organisms containing novel combination of genetic material not obtained through the use of modern biotechnology should not be considered as LMOs in the context of the CPB.
12	7-11	It should be underlined that other techniques might fall under the CPB definition only if they overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection.
12	34-36	It is worth to mention that SB organisms developed so far as pharmaceuticals for humans also include attenuated viruses and not only SB organisms being used as biofactories. See e.g. Mueller et al. Live attenuated influenza virus vaccines by computer-aided rational design. Nat Biotechnol. 2010. 28(7):723-6. doi: 10.1038/nbt.1636. Epub 2010 Jun 13.
14	2-9	The INzyme technology is a good example showing how difficult it is to clearly define what Synthetic Biology is. This technology uses a classical recombinant DNA technique and its novelty resides in its intended use only. We do not think its assessment would lead to any particular challenges.