Comments on the draft documentation on new and emerging issues – deadline 20 September 2013

Possible Gaps & Overlaps

Page	Line	Comment
3	15-23	Include SMO's within the scope of "biological diversity" and advocate that scientific laboratories are a "source". However, within the broad definition of biological diversity, should also advocate for sub-categories distinguishing naturally evolved organisms from those that are synthetically derived/ created by humans.
3	30-35	SMO's are new strains and should count as "species". The authors need to distinguish between the biodiversity of naturally evolved organisms and that of synthetically derived organisms.
5	23-30	All of the above falls into the broad category of "biotechnology" but that sub-categories should be defined that differentiate between SB biotechnology that works with living organisms vs. SB biotechnology that works with cell-free biochemical pathways, protocells and xenobiology, which would fall under either biological systems or more likely biological derivatives.
6	23-28	Naked DNA and plasmids should be included in the definition of LMO's and subject to the CBD's guidelines regarding biosafety.
6	30-34	The synthetically-altered microbes would be LMO's but the target chemicals produced would not be if they are not living and/or do not contain genetic material.
6	36-42	Authors should consider protocells to be genetically modified organisms (GMO's) but not LMO's.
6	44-45	If they have metabolic activity, they should be considered living.
7	4-9	SB research does not present novel risks compared to traditional biotechnology, but that it does present novel opportunities for new tools, methods, technology and approaches to their biosafe utilization and containment to prevent their use from altering habitats, food webs and biodiversity.
7	33-42	The potential benefits of the field of SB, in terms of presenting novel opportunities for new tools, methods, technology and approaches to their biosafe utilization and containment/biosafety, should be promoted.
8	1-10	Unintentional releases should be considered "releases".
8	25-27	Comprehensive risk-return analysis should be performed using all available information. The potential returns need to significantly outweigh the risks.
8	32-39	Some level of funding should be specifically allocated and focused to SB risk research, risk assessments for accidental or intentional non-contained use, or low-probability/high-

		impact events.
8	42-48	As well as using the new opportunities presented by the field of SB itself to create more effective, internally engineered containment mechanisms such as inducible designer proton channels that will eliminate the cells viability in the open environment.
9	14-20	SB biosafety mechanisms and technologies should be shared throughout the industry, or if proprietary, should be sublicensed to any and all interested parties at a minimal cost to promote it's broad and widespread adoption.
10	10-15	The applicability of exemptions to certain CPB provisions are considered for LMOs produced through SB and this should be commended. It is also appropriate to reference directly Annex III of the CPB. Annex III is appropriate for SB when the SB or SB derived product contain detectable novel combinations of replicable genetic material .
10	45-50	The assertion that the products of SMOs are within the CPB is not consistent with other determinations made under CPB. Many of these products would not contain detectable novel combinations of replicable genetic material, the established threshold under CPB Article 20(3(c)); CPB Annex I(i).
11	3-13	As noted, DNA and parts produced through SB have been transported through postal mail for the past decades. And naked DNA does not meet the definition of an LMO. With respect to inserting naked DNA into living cells for transport, this represents a temporary condition where the cells are not intended for release and should be considered a contained use and exempt from the CPB.
11	21-24	Naked DNA and constituent parts produced through SB do not meet the CBP definition of an LMO. An LMO any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids; "Modern biotechnology" means the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;
11	31-33	Any attempt to reform the CPB to include a broader interpretation of "transit" and "transboundary movement" of DNA information by explicitly requiring "those who

		retranslate digital code into a physical LMO to be subject to prior informed consent procedures" would stop academic research and prevent any bioeconomy development by signatories.
11	41-43	Expansion of 'novel combination' would therefore include any mutagenesis techniques – including chemical and UV and thus, would create an arbitrary difference in definitions based on process without regard to similarity of the products.
12	22-32	The exclusion of pharmaceuticals for humans under CPB is appropriate and should be extended to both SB derived products and SB biofactories as well. It is important to highlight that this same exclusion should apply to veterinary pharmaceuticals.
12	47-51	Continued research and development of vaccine development, whether for humans or animals may be discouraged if SB are further included within CPB.
13	18-41	Under the CPB, provisions for Advanced Informed Agreement (AIA) do not apply to the transboundary movement of LMOs "destined for contained use undertaken in accordance with the standards of the Party of import" (CPB Art. 6(2)). This same exemption for contained use should hold for SB products. Contained use by definition does not offer a threat to biodiversity. Further, concerns that domestic risk assessment procedures are not being consistent with Annex III is an overall discussion related to compliance with CBP and should not be part of SB discussions.
14	40-43	As described, Annex III of the Protocol is focused on general principles, points to consider and methodology are fully applicable to living organisms produced through SB and may also apply to "products thereof" that contain "detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology"
15	0	This section considers the application of the Nagoya Protocol (NP) to synthetic biology. It is critical to balance our need to support fair and equitable benefit-sharing while protecting and encouraging innovation of important technologies. We must proceed with prudence such that the NP and other policies don't stifle scientific advancement by allowing those achievements to become shared public information without reward for the investment of time and creative thought.
15	10-13	It is commendable to acknowledge the speculative nature of this discussion given that the scope of the Protocol is uncertain, and it has not yet been implemented. It stands to reason that <u>no decisions about its application to synthetic biology can be made in the short term.</u>
15	37-38	In accordance with the International Civil Society Working Group on Synthetic Biology (ICSWGSB), digital information would not be considered a "genetic resource" under the

		current NP which “addresses genetic resources where indigenous and local communities have the established right to grant access to them” (About the Nagoya Protocol website, http://www.cbd.int/abs/about/).
16	10-19	In accordance with the ICSWGSB, “products derived from natural sequences using synthetic biology tools such as directed evolution techniques” would not be covered under the current NP. Furthermore, BIO and its members do not believe the NP should expand its scope to encompass these products. This expansion would distort its intent to achieve “the conservation and sustainable use of biodiversity” by going much further down the value chain than is appropriate.