Biotechnology Industry Organization

January 31, 2016

Peer Review Comments to the Convention on Biological Diversity (CBD) Reports:

"UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TO PARAGRAPH 7(b) OF DECISION XII/24 ON NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY"

And

Final Report: "REPORT OF THE ADHOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY"

UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TOPARAGRAPH 7(b) OF DECISION XII/24 ON NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY	
Paragraph 4	The AHTEG's synthesis of views in the moderated open-ended online forum indicates there is disagreement on whether or not synthetic biology is a new and emerging issue for conservation and sustainable use of biodiversity. However, the definition of synthetic biology adopted in the AHTEG report would resolve this question by affirming that synthetic biology is not a new and emerging issue. The definition accurately recognized that "synthetic biology is a further development and new dimension of modern biotechnology,' rather than a new issue.
Paragraph 26 (C)	The production of living organisms through modern biotechnology and synthetic biology is similar <u>but the genes</u> and nucleic acid molecules transferred into the recipient organisms <u>differ</u> in that nucleic acids **transferred through modern biotechnology exist in nature *but not* those transferred through synthetic biology**. Therefore, some techniques of synthetic biology may or may not be readily classified as "*in vitro* nucleic acid techniques". This distinction is without *any* scientific merit but it is a statement with significant potential for harm. Very simply, since the dawn of "modern biotechnology" genes have been chemically synthesized especially for the purpose of host codon usage. So even recombinant human insulin was a synthetic gene that *does not exist in nature*. This line in the report perpetuates a narrative by anti-technology groups that attempts to differentiate old molecular techniques as a form of 'cutting and pasting' naturally occurring genes between organisms with new, troublesome synthetic biology's ability to create a gene that has never existed in nature on a computer, synthesize it, and insert it into an organism. Pushed hard enough this serve as a chaos wedge to loop historic biotechnology into 'new' technology and new regulatory frameworks.

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Final Report: "**REPORT OF THE ADHOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY**"	
Paragraph 28	This implicates all three 'categories' (LMOs, nonliving, and products) and states that all manner of fermentation derived renewable chemicals and nonliving extracts, etc, will be under new review space which is unnecessary.
Paragraph 31	Digital genetic information is a potential quagmire. It is not clear that those advocating this have thought through implications, including newer scientific information calling into question geographic uniqueness of genetic information. Meaning that while it has been a historic practice to prospect where culturable microbes are easily found in 'diversity hotspots', the advent of sequencing technologies have found much wider geographic dispersion of genetic information. If a gene, or its homolog, is found in multiple public databases, it will be very complicated to find out who has "ownership" for it, and given US patent rulings (Myriad Genomics) it is not clear what 'ownership' of a gene sequence from nature might mean. Digital sequence information reprises in **Paragraph 39** and **Paragraph 41**
Paragraph 38	The desire to include 'products of' synthetic biology into additional biosafety frameworks is very troubling for any entity doing natural product research and development. This should be removed since the science and/or technology creating the desired product is protected by the inventor's intellectual property rights. This is reprised in **Paragraph 40 most importantly it resurfaces as an element of Paragraph 57**
Paragraph 42	Very troubling, the definition of 'components of synthetic biology" is given in **Paragraph 32**, and specifically exemplified by 'a DNA molecule'. When the definition of 'components' is inserted into the sentence in this paragraph, it implies that existing national legislation is not adequate to control the 'exchange, distribution and commercialization' *of DNA molecules* and resulting new chemicals and products thereof. On what basis is that an issue, since DNA has been exchanged and distributed globally forever, but including since the advent of modern biotechnology?
Paragraph 46	Part of the argument on risk assessment promulgated here is that synthetic biology may have a higher level of uncertainty associated with it (see last sentence of Paragraph 45). So one can intuitively see how assessment can be benefited by 'reasoning based on evidence' and one should applaud that. How is uncertainty benefited by forward looking scenarios, which, by the construction of the sentence, might be contrasted with being based on evidence?
Paragraph 49	The report vacillates between 'the *potential*' to engineer more complex organisms (Paragraph 4) and a statement of fact, 'due to its higher level of complexity'. Can be vs must be needs to be more consistent and there is little logic to argue that synthetic biology MUST BE more complex, or else how are High School students competing in IGEM teams? These inconsistencies in thinking needs to logically articulated which is lacking in the report.

Paragraph 52	The listings between the potential benefits and adverse effects are not balanced. There is 'lumping' in the benefits list [see entry (d), where ag/ag forestry is lumped, as are pesticide usage and pollinator benefits]. These are separated into elements on their own in the adverse list. Secondly, adverse list item (c) is not unique to synthetic biology; as it was a key consideration all the way back to Asilomar discussions. Potential adverse objective 3 (l) and (m) all reprise the argument about digital DNA information and show that this is a total quagmire. Element (n) is essentially uninterpretable in that these are not exclusive terms. Not only because a single entity can use both business models (patenting and open source distribution) but because many proponents of open source synthetic biology focus that on the level of 'parts' and admit that proprietary combinations of open source parts should be subject to patent protection. Potential adverse element (o) is a behavior (will not necessarily support…), so it is unclear why a behavior is an aspect of this part of the report. It is also probable that they might be willing to support it but obstructed from doing so by misguided polices promulgated on their behalf, especially since **Paragraph 68** notes that they were not there to represent themselves.
Paragraph 57	This paragraph unambiguously shows an intent, under the unclear cover of 'comprehensiveness', to incorporate products of synthetic biology (for example natural products produced by a synthetic biology organism)
Paragraph 66(a)	The definition still seems far from 'operational'. How does one establish operational protocols to regulate 'accelerating the understanding' of an organism? **Paragraph 32** and others discussed two other definitions (components and products) and these two terms are missing from the definition despite the Report arguing that all three (organisms, components and products) are subject to the Convention (**Paragraph 38**).