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Subject: Further info on the outcomes of the AHTEG on Synthetic Biology

Hi all,

I participated in a conference call with Jim Louter to listen to a verbal debrief of his participation in the AHTEG on Synthetic Biology. There were a few points that I thought were worth highlighting for you all. They're all in relation to the draft report of the AHTEG, which I've attached here.

1) Paragraph 24 includes the operational definition of Synthetic Biology. Jim pointed out that use of the term "modern biotechnology" in the definition gives it firm linkages to the Cartagena Protocol, in which modern biotechnology is defined in fairly narrow terms [*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.*] This was preferred over biotechnology, which is defined much more broadly in the CBD [*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*].

2) For organisms derived from synthetic biology, there was general agreement that these will fall under the definition of LMOs and be covered by the Cartagena Protocol and overall there is a comprehensive framework in place (e.g., paragraphs 34 and 38). Jim mentioned that no one at the AHTEG could come up with a real example of an organism of synthetic biology that wouldn't be an LMO. However, there are a few places in the document where this is undermined, such as paragraphs 35 and 79.

3) Jim mentioned that there was a strong push, particularly by the NGOs, to equate non-peer reviewed publications (e.g. blog posts, website content, self-published articles) with peer-reviewed publications in terms of their value. See for example paragraph 46, which mentions that synthetic biology should be assessed with an appropriate balance between evidence as well as rational arguments. "Rational arguments" could be interpreted quite loosely by NGOs.

4) It was agreed that components and products of synthetic biology are non-living and therefore do not fall under the scope of the Cartagena Protocol (Paragraph 33). It was unclear if there were potentially gaps in oversight for products and components of synthetic biology. It was discussed that oversight likely existed, e.g. for chemicals, drugs, cosmetics, etc., but there is no single, overarching framework and so oversight is described as fragmented. Similarly, it was noted that there could be gaps in oversight under the Convention and its Protocols for components and products of synthetic biology. Jim was of the opinion that we likely had sufficient systems in place since products of synthetic biology would be equivalent to their non-synthetic biology counterparts and would be regulated similarly.

Jim expects that a new draft AHTEG report will be circulated to AHTEG members for review that should take on board final discussions. Much of the mark up in the attached document should be reflected in the next iteration. Following this, there should be additional activity at SBSTTA20 [Subsidiary Body on Scientific, Technical and Technological Advice], which is April 25-29, 2016.

Regards,
Jaimie

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