**New Zealand Comments on Synthetic Biology papers**

**Update report and synthesis of views in response to paragraph 7 (b) of decision X11/24 on new and emerging issues: synthetic biology - UNEP/CBD/SYNBIO/AHTEG/2015/1/2**

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| Paragraph number | comment |
| 11 | Agree.  |
| 14 | Support. This assessment could involve controlled release prior to full release to gain a better understanding of how an organism or product performs outside strict containment. |
| 16 | We support the assessment of risks as well as benefits of all components, organisms and products that can be released into the environment, against the objectives of the Convention, including those that are not capable of replicating or reproducing. However specific attention and focus must be paid to those capable of replicating or reproducing. |
| 17 | We support a scientific, case-by-case approach to assessment of risk of components, organisms and products derived from synthetic biology. We agree that an increase in the complexity of synthetic biology may lead to increased uncertainty of outcomes. We question that this will directly “lead to the need for stricter measures to prevent damage to biodiversity”. Increased uncertainty may lead to more complex risk assessment, but not necessarily require increased stringency.  |
| 19 | We note there is increasing discussion internationally about the most appropriate approach to risk assessment for LMOs/GMOs. Process is not necessarily a proxy for risk, but can be viewed as a regulatory trigger. We support the consideration of both process and output in the meantime and further discussion about what this might look like. We also support the statement that changes in products may not be easily detectable and an assessment of impacts can only be performed if the process is taken as a starting point. |
| 20 | Agree. The absence of an operational definition of synthetic biology resulted in somewhat circular discussion. |
| 21 | Agree. |
| 23-27 | We support further discussion of the ‘boundary’ (similarities and differences) between modern biotechnology and synthetic biology. |
| 25 | We agree with this statement. There is a continuum of advances which will no doubt continue to expand over time and any process, risk assessment framework or regulatory regime needs to be responsive to future developments. |
| 27 | Discussion needs to centre on managing the risk and or impacts of these activities. We also question which organisms fall under the scope of the Cartagena Protocol on Biosafety, whether it provides sufficient risk management, and how any residual risk issues will be managed. Does the current risk management guidance take into consideration organisms and products derived from synthetic biology? |
| 29 | We support the statement “defining synthetic biology… is a necessary step to determine if synthetic biology is objectively unique from other already-existing areas, and whether or not the outcomes of its research and development require new approaches to regulation”. A definition of synthetic biology will help target the level of measures, guidance documents and risk assessments necessary. Associated with this we consider there is a need to consider the span, application, and functionality of the Convention’s existing instruments, particularly the Cartagena Protocol. |
| 31 | We support that a starting point is to determine which aspects of synthetic biology (if any) would fall outside the Cartagena Protocol. This should be followed by whether such aspects are covered by other instruments or need to be captured at all.  |
| 34 | We agree that future-proofing is important. Inclusion and exclusion criteria will soon become out of date as a result of the advances in this field. |
| 47-48 | Echoing our comments in 23-27, we recommend that a more detailed analysis is undertaken of the application of the Cartagena Protocol to evolving biotechnology, particularly when processes do not involve novel combination of genetic material, replication of genetic material, modification, or in vitro nucleic acid techniques, before new instruments are considered relating to living organisms. We want to avoid leaving unidentified gaps and/or unnecessary over-regulation.  |
| 49 | We ask that the statement “…current international regulatory instruments are not adequate in that they are fragmented and do not comprehensively address all concerns related to the products of synthetic biology…” is tested further. It may be that there are limitations to the Cartagena Protocol for living organisms, or chemical management regimes, or that some of the issues are more country specific. |
| 51 | The Updated Report raises questions that some living organisms may not necessarily fall within the scope of the Cartagena Protocol (e.g. in para 26). The Updated Report does not contain enough information to state that all current living organisms resulting from synthetic biology are adequately regulated within the scope of the Convention and its Protocol. An effective and transparent review of the current framework is critical for ensuring a robust framework. The Updated Report identifies gaps in our knowledge. We agree with the view that existing information is insufficiently conclusive to state whether or not existing regulations are adequate to regulate living and non-living components, products and organisms produced by synthetic biology. |
| 52 | Agree. |
| 53 | Agree. We consider that responsive processes that can keep pace with new developments in modern biotechnology and effectively manage risks, are needed.  |
| 55 (a) | With regard to the reference to “destined to contained use” there is always some level of risk of unintentional release and this should always be factored into the containment management regime.  |
| 55 (e) | We note that IPBES is in the process of developing protocols for engagement with ILK and this may make it easier to assess the impacts (including socio cultural aspects) of these activities on traditional practices, knowledge, resources and ILK communities. |
| 57 (a) | Re a “system that not only encourages innovation”, if a framework is required to consider the impacts of synthetic biology, any criteria should be linked to the objectives of the Convention. |
| 57 (b) | Agree.  |
| 57 (c) | Agree. There are very rare circumstances (e.g. emergency provisions related to a global epidemic) where less rigorous processes may be agreed to. |
| 57 (d) | Support. |
| 57 (f) | Support. |
| 57 (h) | Oppose. We are not convinced the findings from this Report are sufficiently conclusive that there is “a need to develop an international framework to cover the organisms, components or products of synthetic biology techniques”. Assessment of socioeconomic impacts is likely to be country specific. |
| 57 (j) | Support. We also support the call for more work on harmonisation, but also importantly on identifying best practices. |

**Report of the Ad Hoc Technical Expert Group on Synthetic Biology – UNEP/CBD/SYNBIO/AHTEG/2015/1/3**

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| Paragraph number | comment |
| 22 | Support. Development of an operational definition is a pragmatic approach that will ensure greater consistency and understanding of the issues at hand. The online forum discussions were hindered by not having a single definition, which meant it was difficult to identify what is and is not currently covered by the Convention’s framework. |
| 24 | This definition seems focused on biological/living entities. We recognise that synthetic biology is not a technique per se but rather a wide field representing techniques that can modify and make living and non-living entities, which could have possible impacts on the objectives of the Convention. The definition should reflect this. |
| 27 | Support. However more clarification is necessary as to how this baseline will be developed, by whom and how it will be applied. |
| 29 | We support the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.  |
| 30 | The proposed online platform will provide for exchange of information and experience. |
| 32 | Agree. |
| 33 | The consideration of their similarities and differences may provide enough to differentiate the organisms, but with science advances and development of different types of organisms the similarities and differences may become less clear between LMOs and Synthetic Biology developed organisms.  |
| 35 | We support further work to assess which organisms of synthetic biology currently in the early stages of research and development would fall under the definition of LMO under the Cartagena Protocol on Biosafety.  |
| 36 | Agree.  |
| 38-42 | It would be useful to have more specific information about which aspects of the wide field of synthetic biology fall within the Convention’s framework (the definition perhaps does not provide sufficient guidance), and specific areas of concern/priority in relation to its objectives.We note the range of regulatory approaches and capacity internationally. We support the promotion of information and best practice sharing to develop and strengthen domestic regimes. |
| 44-48 | We agree that the higher level of complexity of synthetic biology (compared to classical genetic modification) could lead to decreased familiarity of an organism developed through synthetic biology. This will need to be taken into consideration of as part of the risk assessment. We support evidence-based, case-by-case assessments, recognising the particular context in which the application is used. To minimise the risk of unintentional negative impacts outside of containment, until more understanding and knowledge of the “product” is gained, controls could be imposed on its release. A case-by-case approach would recognise specific national settings and potential cross boundary implications. |
| 55 | Support. |
| 57 | Agree.  |
| 59 | It would be useful to indicate which matters need to be addressed in the current risk assessment. Flexibility will be needed to ensure countries can meet their domestic priorities in the use of indigenous biodiversity. Agree with the development of guidelines that will be specific to the areas where discrepancy is high among the different Parties. |
| 66 (a) | We question whether this definition takes sufficient account of non-living entities. |
| 66 (b) | Agree.  |
| 66 (c) | Support. We ask that this information is shared. |
| 66 (e) | Support.  |
| 66 (f) | Agree.  |
| 66 (j) | We support the assessment of potential gaps under the Convention’s framework, not just with regard to components and products, but also organisms. |