**CONVENTION ON BIOLOGICAL DIVERSITY**

**SYNTHETIC BIOLOGY**

**NEW ZEALAND SUBMISSION**

**April 2015**

Please find below New Zealand’s comments and observations regarding the topics raised by the CBD Secretariat in Notification 2015-013.

*1. How to address the relationship between synthetic biology and biological diversity*

COMMENT:

-Under the CBD and the Cartagena Protocol, the focus of the relationship is the impact on the conservation and sustainable use of biological diversity. To be consistent, discussions of synthetic biology should be in the context of potential impacts on the conservation and sustainable use of biological diversity. The table below illustrates the approach taken under the Convention and the Protocol.

Table 1: Relevant text from CBD and the Protocol

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| CBD Article 7Identification and monitoring | (c) Each Contracting Party shall, as far as possible and as appropriate… “identify processes and categories of activities which have or are likely to have significant adverse impacts *on the conservation and sustainable use of biological diversity*…”  |
| CBD Article 14Impact assessment and minimising adverse impacts | 1(a). Each Contracting Party shall, as far as possible and as appropriate… “introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to *have significant adverse effects on biological diversity* with a view to avoiding or minimizing such effects…” |
| CBD Article 16Access to and transfer of technology | 1. Each Contracting Party… “undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are *relevant to the conservation and sustainable use of biological diversity* or make use of genetic resources and do not cause significant damage to the environment.” |
| CBD Article 19Handling of biotechnology and distribution of its benefits | 3. “…biotechnology that *may have an adverse effect on the conservation and sustainable use of biological diversity*.”  |
| CP Article 1Objective | “…LMOs resulting from modern biotechnology that may have *adverse effects on the conservation and sustainable use of biological diversity*, taking also into account risks to human health, and specifically focusing on transboundary movements.”  |
| CP Article 3Use of terms | LMO: “any living organism that possesses a novel combination of genetic material obtained through use of modern biotechnology.”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.” |
| CP Article 4Scope | “…living modified organisms *that may have adverse effects on the conservation and sustainable use of biological diversity*, taking also into account risks to human health.”  |
| CP Articles 15 and 16Risk assessment and risk management | -effects of LMOs *on the conservation and sustainable use of biological diversity* |

*2. The similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques;*

-The Cartagena Protocol definition of LMO – “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” – is based in part on the process on which the organism is modified. The language “organisms, components and products of synthetic biology techniques” is also process- or technique-based.

-Organisms made via synthetic biology techniques may have similarities to LMOs as defined in the Cartagena Protocol.

-Components and products made via synthetic biology techniques are different to LMOs, as they are not living organisms.

-These components and products may have more in common with chemical substances, given they are not living organisms.

Table indicating how Cartagena Protocol definitions vary with those under New Zealand Legislation

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| Cartagena Protocol and LMOs | Synthetic biology terminology in CBD | HSNO – genetically modified organisms | HSNO – hazardous substances |
| -any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology-definition based on process (use of modern biotechnology) | -organisms, components and products of synthetic biology techniques-focus is on process (“techniques”) | -unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—(a) have been modified by in vitro techniques; or(b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques-focus is on identifying the class of organisms subject to regulation. Genetic modification must be caused by the in vitro technique in order for the organism to be regulated.  | -unless expressly provided otherwise by regulations, any substance—(a) with 1 or more of the following intrinsic properties:(i) explosiveness:(ii) flammability:(iii) a capacity to oxidise:(iv) corrosiveness:(v) toxicity (including chronic toxicity):(vi) ecotoxicity, with or without bioaccumulation-definition based on properties |

*3. Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques.*

-The adequacy of existing national, regional and/or international instruments will depend to a large extent on what is being regulated. Without a clear definition of synthetic biology – and therefore lack of specificity about relevant instruments – adequacy is difficult to assess.

-New Zealand believes that more work is needed to understand how the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and the Strategic Approach to Integrated Chemicals Management (SAICM) may apply to non-living components and products derived from synthetic biology techniques. It would be useful for the CBD Secretariat to include relevant information from these regimes in further analyses of synthetic biology.

*4. An operational definition of synthetic biology, comprising inclusion and exclusion criteria*

*-*New Zealand does not have any suggestions for an operational definition of synthetic biology. However, we do note that different approaches can be taken to developing such a definition. Definitions may be based on the process/technique used (such as with LMOs under the Cartagena Protocol), they may be based on criteria that define organisms, components and products of synthetic biology, or a definition could be based on a combination.

*5. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols*

-New Zealand underlines that robust and effective risk assessment and risk management procedures are essential to maximise the benefits and reduce risks to the conservation and sustainable use of biodiversity.

*6. Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes;*

-In New Zealand, new organisms and hazardous substances are regulated under the same statute: the Hazardous Substances and New Organisms Act (HSNO Act).

-‘Outputs’ of synthetic biology techniques may be regulated by the HSNO Act if they come within the definition of an ‘organism’ and ‘new organism’ in the Act. ‘Organism’ is widely defined in the Act and includes a genetic structure (other than a human cell) that is capable of replicating itself, whether that structure comprises all or part of the entity. The definition of ‘new organism’ includes organisms belonging to species that were not present in NZ prior to July 1998 and GMOs. The definition of a GMO is very broad (organisms whose genes or genetic material have modified by in vitro techniques). However, regulations may provide that certain organisms are not GMOs.

-If there is uncertainty about whether an entity is a GMO (or even an organism), there is a formal determination the Environmental Protection Authority can undertake pursuant to the HSNO Act.

-Regarding the regulation of products or components of synthetic biology, possible regulation under the HSNO Act depends on intended use of the substance. Under the HSNO Act, a substance is classified as a ‘hazardous substance’ if it meets the threshold defined by the ‘hazard classification system’. Whether or not the substance comes from a natural source is irrelevant (synthetic chemistry is a well-established field of science), and the threshold relates to the particular compound as well as the concentration.

-Classification of a substance as a ‘hazardous substance’ depends on an assessment using the ‘hazard classification system’. Specifically, the associated toxicity data package is assessed. The two examples below illustrate the assessment, and how the outcomes vary with different toxicity data packages.

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| **Citric acid** |
| *Concentration* | *Hazard Classification* |
| 10%+ concentration | skin irritant (6.3B) |
| 3%+ conc. | eye corrosive (8.3A) |
| between 1-3% conc. | eye irritant (6.4A) |
| < 1% conc. | Non-hazardous |

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| --- |
| **Sodium chloride (table salt)** |
| *Concentration* | *Hazard Classification* |
| 16.7%+ concentration | oral toxicity (6.1E oral) |
| 10%+ concentration | eye irritant (6.4A) |
| < 10% conc. | Non-hazardous |

*7. The degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity;*

Please see response to #3 above.

*9. Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance; and*

Please see response to #6 above.

*10. Further information on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.*

No comment.