**CONVENTION ON BIOLOGICAL DIVERISTY**

**SYNTHETIC BIOLOGY**

**NEW ZEALAND SUBMISSION**

**JUNE 2017**

Please find below New Zealand’s comments regarding the topics raised by the CBD Secretariat in Notification 2017-025. New Zealand provides its comments within the context of its legislative framework for the regulation of genetically modified organisms (GMOs), the Hazardous Substances and New Organisms Act. Among other things, this legislation implements relevant New Zealand obligations under the Convention on Biological Diversity and its Cartagena Protocol.

New Zealand’s comments should be considered in the context of the objectives of the Convention on Biological Diversity and its Cartagena Protocol.

*a) Research, cooperation and activities*

New Zealand supports the conduct of research, as necessary, into the impacts of developments in genetic modification technology on the conservation and sustainable use of biodiversity.

In terms of research by relevant organisations, the Royal Society of New Zealand has convened a multidisciplinary panel of New Zealand’s leading experts to consider the implications of gene-editing technologies for New Zealand, including research, ethical, social, legal, regulatory, environmental and economic considerations.  This panel will also consider New Zealand’s unique cultural perspectives. More information can be found at <http://royalsociety.org.nz/what-we-do/our-expert-advice/all-expert-advice-papers/gene-editing/>.

*b) Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention*

New Zealand does not have specific evidence to submit at this point as to the benefits and adverse effects of synthetic biology regarding the three objectives of the Convention.

However New Zealand would like to reiterate that robust and effective risk assessment and risk management procedures should be in place in order for Parties to be able to consider evidence of the benefits and adverse effects of synthetic biology. New Zealand supports the sharing of real life case-studies through the Biosafety Clearing-House.

*c) Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks*

Risk assessments of GMOs (which include organisms produced through synthetic biology, *see (e) below),* are carried out under the provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO Act further sets out a specific Methodology that must be undertaken as part of the assessment and decision-making process. The HSNO Act also sets out Minimum Standards that require effects on native species, biodiversity, and natural habitats to be considered as part of the risk assessment and decision-making process. If any of the Minimum Standards cannot be met, then any application must be declined.

This risk assessment framework sets a very high threshold for the release of any GMO. Under this framework, in place for nearly 20 years, only two GMOs, a trial cancer therapy and a veterinary vaccine, have been approved for conditional release (i.e. release with controls to manage low-level risk).

Full details of the risk assessments that underpinned these approvals can be found at <http://www.epa.govt.nz/news/epa-media-releases/Pages/EPA-approves-use-of-virus-for-liver-cancer-treatment-trial.aspx> and http://www.epa.govt.nz/search-databases/HSNO Application Register Documents/GMR07001.doc.

Information regarding applications to undertake field tests of GMOs in New Zealand (including details of risk assessments and controls imposed on these field trials) are publically available at: <http://epa.govt.nz/new-organisms/popular-no-topics/Pages/GM-field-tests-in-NZ.aspx>

*d) Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology*

It is illegal to import any GMO (including organisms developed using synthetic biology, see (e) below) into New Zealand without approval under the HSNO Act.

We provide the following example of New Zealand’s risk management process for genetically modified seeds and plants for planting.

Genetically modified crops and their seeds are defined as new organisms under the HSNO Act. This Act deems unlawful the import, development, field-testing and release of any organism without approval from the Environmental Protection Authority. The HSNO Act is enforced at the New Zealand border under section 28 of the Biosecurity Act 1993.

Importers must take appropriate precautions to ensure that their consignments do not contain unapproved genetically modified material. No genetically modified seeds or plants have been approved for release into the New Zealand environment, which means that strict rules around seed imports are applied to make sure unapproved genetically modified seeds do not arrive in the country.

New Zealand uses reliable test methods to minimise the likelihood of unapproved genetically modified seeds being released into the environment. DNA testing to verify non-GMO status is an import requirement on seeds for plant species well known to have genetically modified varieties and commercialised worldwide, e.g. maize, canola, and cotton. In the case of certain species of plants for planting, the importers are required to sign and present a non-genetically modified declaration as part of the import requirements.

*e) Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology*

New Zealand implements its obligations under the Convention and the Cartagena Protocol through the provisions of the Hazardous Substances and New Organisms (HSNO) Act. Outputs of the manipulation of genetic material may be regulated by this Act if they come within the definition of an ‘organism’. ‘Organism’ is defined in the HSNO Act and includes a genetic structure that is capable of replicating itself, whether that structure comprises all or part of the entity. A ‘new organism’ includes all GMOs. The definition of a GMO in the HSNO Act is very broad: specifically, organisms whose genes or genetic material have been modified by *in vitro* techniques, or are inherited or otherwise derived therefrom. There are organisms that fit this definition that are not to be regarded as genetically modified, as specified in regulations. All synthetic biology organisms conform to the definition of a GMO in the HSNO Act and are thus regulated under the Act.

Potential environmental impacts (including impacts on biological diversity) of any GMO in New Zealand are assessed on a case-by-case basis. If there is uncertainty about whether an entity is a GMO (or even an organism) there is a formal determination process the Environmental Protection Authority can undertake specified in the HSNO Act.

*f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology*

Under the HSNO Act, all members of the community may comment on a publicly notified application for release of a GMO.

In addition, sections 6 and 8 of the Act contain specific provisions requiring consultation with Māori (New Zealand’s indigenous people) and ensuring that the principles of the Treaty of Waitangi are taken into consideration by Government. The Act specifies that the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred sites), valued flora and fauna and other taonga (treasures) be taken into account.