**Information of the Netherlands**

**CBD Notification 2018-103 - Submission of information on synthetic biology**

The Conference of the Parties invites Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide the Executive Secretary with relevant information to contribute to the work of the AHTEG, namely on:

**(a)          The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17;**

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| *Criterion 1: Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work* |
|  | We consider that organisms, components and products of synthetic biology can have neutral, positive or negative effects on biodiversity. This has to be assessed on a case-by-case basis. Since synthetic biology may result, on a case-by-case basis, in potential negative effects on biodiversity, synthetic biology is relevant for the implementation of the objectives of the Convention and its existing programmes of work. |  |
| *Criterion 2: New evidence of unexpected and significant impacts on biodiversity (2)* |
|  | Up to now, there is no evidence for unexpected and significant impacts on biodiversity resulting from synthetic biology.  |  |
| *Criterion 3: Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity* |
|  | The speed of development of organisms, components and products from synthetic biology is high. Since some of these developments may result in potential negative effects on biodiversity, we also consider the urgency of addressing synthetic biology in the effective implementation of the Convention to be high. Potential negative effects -if any- will most probably result from living organisms obtained by synthetic biology. Organisms obtained by synthetic biology that are (or will be) introduced in the environment in the near future fall under the definition of a living modified organism (LMO) and their safety is therefore addressed under the Cartagena Protocol on Biosafety. Taking this in account, addressing synthetic biology in the effective implementation of the Convention does not have high urgency. Urgency would be higher for organisms obtained by synthetic biology that do not fall under the definition of an LMO and that could pose a negative environmental effect. |  |
| *Criterion 4: Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity* |
|  | All organisms obtained by synthetic biology and that are released so far are LMOs. The actual geographic coverage and potential spread is therefore equal to the actual geographic coverage and potential spread of the current LMOs. |  |
| *Criterion 5: Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity* |
|  | All current and near-future organisms to be released into the environment obtained by synthetic biology are LMOs and their safety is therefore addressed under the Cartagena Protocol on Biosafety. So far no LMOs have been released that negatively impact conservation and sustainable use of biodiversity and where tools are absent or limited to mitigate these negative effects. However, in the future fast replicating and fast-spreading LMOs (such as mosquitoes) with engineered gene drives can be released that may pose negative effects on biodiversity and where tools to mitigate these effects are so far limited. |  |
| *Criterion 6: Magnitude of actual and potential impact of the identified issue on human well-being* |
|  | As stated before, we consider that organisms, components and products of synthetic biology can have neutral, positive or negative effects on biodiversity. The magnitude of these potential effects cannot be predicted in a generalized manner and has to be assessed on a case-by-case basis. |  |
| *Criterion 7: Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity* |
|  | Organisms, components and products of synthetic biology can have neutral, positive or negative effects on several productive sectors such as agriculture, medical sector, in biofuel production and food sector (e.g. additives, colorants, flavourings).  |  |

**(b)          New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group in December 2017, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process**

We want to refer to the EU joint submission to this notification with respect to recent activities and developments at the EU level. This EU submission will be sent as a separate submission.

In addition, there have been quite some developments in research on synthetic biology. These have been documented in literature, newsletters, websites (for example from start-up companies) and through iGEM competitions. In the Netherlands a newsletter on new developments and applications (titled ‘the Symbiont’) is published on a regular basis, but is only available in Dutch.

Some reports that have been published since 2017 that highlight new developments and concrete applications of modern biotechnology, expected timeline and the consequence for risk assessment are:

-Preparing for future products of biotechnology (2017) Report of the National Academy of Science

*https://www.nap.edu/catalog/24605/preparing-for-future-products-of-biotechnology*

-Assessment of human health and environmental risks of new developments in modern biotechnology - a policy report (2018). RIVM report (Hogervorst et al.).

*https://www.rivm.nl/publicaties/assessment-of-human-health-and-environmental-risks-of-new-developments-in-modern-biotechnology*

The RIVM report is based on three reports commissioned by RIVM that describe new developments in red, white and green biotechnology, among others. References can be found in the report.

 **(c)           The current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account the traits and species potentially subject to release and the dynamics of their dissemination**

Potential positive and negative environmental impacts resulting from applications of synthetic biology, including organisms containing engineered gene drives, can only be assessed based on a case-by-case environmental risk assessment. This risk assessment takes into account, among others, aspects such as the specific trait, species and dissemination and for gene drives also the type of gene drive system (low threshold, high threshold gene drive).

For most applications of synthetic biology the current environmental risk assessment methods, used for LMOs, can be applied. However, for some applications this method may not be the most suitable method to use or more knowledge or data is necessary to perform an adequate risk assessment. In the RIVM report mentioned under b) (see link below) a framework was developed to test the use of the existing risk assessment methodology for 30 new or future applications of modern biotechnology, including synthetic biology. The current risk assessment method appeared to be adequate for about half of these. For the other half, the risk assessment method did either not seem to be adequate because it did not concern living organisms, or insufficient knowledge or information was available to effectively assess risks. It was not concluded that potential risks of these new or future applications cannot be assessed, however the assessment of the potential impact is more adequate if more knowledge or data are obtained. *https://www.rivm.nl/publicaties/assessment-of-human-health-and-environmental-risks-of-new-developments-in-modern-biotechnology.*

With respect to organisms containing engineered gene drives, a literature report was commissioned by the Dutch Committee of Genetic Modification (COGEM) in 2017, titled ‘Gene drives - Experience with gene drive systems that may inform an environmental risk assessment’. The final report will soon be published on the COGEM website <https://www.cogem.net/index.cfm/en/publications/>

Other information that could be relevant with respect to organisms containing engineered gene drives, is existing information on environmental impacts of biological control agents (such as insects) that have been released in the environment to suppress pest, information from applications of the sterile insect techniques to suppress mosquitoes, or from experiences with insects genetically modified to suppress populations. Some information can be found via the links below.

<https://onlinelibrary.wiley.com/doi/10.1002/9781119255574.ch5>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2946175/>

<https://www.sciencedirect.com/science/article/pii/S2214574515000905>

<https://onlinelibrary.wiley.com/doi/full/10.1111/eva.12286>

**(d)          Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.**

A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as *any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*.

"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids, and "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.

The operational definition of synthetic biology of the AHTEG synthetic biology is as follows: “*synthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems*”.

Based on these definitions, it can be considered that all living organisms developed through synthetic biology so far will fall under the definition of an LMO. In the definition of an LMO, the use of in vitro nucleic acid techniques is not limited to only DNA as genetic material. Therefore living organisms that are built or modified to contain other genetic material than DNA (such as XNA) for replication would also fall under the definition of an LMO.

Examples of living organisms that fall outside the definition of LMOs seem therefore limited to living organisms that do not contain genetic material that can be transferred or replicated. This may apply to some living protocells that are still in an early state of research.