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February 11, 2019

Dear Dr. Paşca Palmer,

In response to your request for information sent on 14 December 2018 (NOTIFICATION No. 2018-103 and appended in this letter as Annex 1), Canada, as a Party, is pleased to provide the following through Canada's National Focal Point in the following 4 areas:

- (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;
- (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
- (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; and
- (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.

With respect to (a), consider the analysis in the attached.



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The analysis in (a) would indicate that some but not all of the criteria are met and therefore, the issue of synthetic biology cannot be said to meet all the criteria in decision IX/29, paragraph 12.

With respect to (b), consider the following for typical citations that can be found regarding developments in synthetic biology and concrete applications of genome editing:

- Engineered insect strains for population and disease control
 - <http://www.synbioproject.org/cpi/applications/engineered-insect-strains-for-population-disease-control/>
- Engineered bacteria to fight soil erosion
 - <http://www.synbioproject.org/cpi/applications/auxin-engineering-bacteria-to-help-fight-soil-erosion/>
- Insect Allies – engineering insects to combat crop stress could be repurposed
 - Kupferschmidt, Kai. "Crop-protecting insects could be turned into bioweapons, critics warn." *Science* (2018).
- Mammalian gene-drives are possible, but suffer from limitations not observed in insects
 - Grunwald, Hannah A., et al. "Super-Mendelian inheritance mediated by CRISPR/Cas9 in the female mouse germline." *BioRxiv* (2018): 362558.
- Computer assisted design tools for synthetic biology
 - Nowogrodzki, A. "The automatic-design tools that are changing synthetic biology." *Nature* 564.7735 (2018): 291.
- Template independent enzymatic DNA synthesis
 - Service, R (2018) New way to write DNA could turbocharge synthetic biology and data storage. doi:10.1126/science.aav6033
- Anti-CRISPR proteins can protect cells against gene-editing
 - Nakamura, Muneaki, et al. "Anti-CRISPR-mediated control of gene editing and synthetic circuits in eukaryotic cells." *Nature communications* 10.1 (2019): 194.
- Machine learning can be used to determine whether gene sequences are of natural or synthetic origins
 - Kunjapur, Aditya M., Philipp Pflingst, and Neil C. Thompson. "Gene synthesis allows biologists to source genes from farther away in the tree of life." *Nature communications* 9.1 (2018): 4425.
- CRISPR-nucleases can be engineered as biological recording devices
 - Sheth, Ravi U., and Harris H. Wang. "DNA-based memory devices for recording cellular events." *Nature Reviews Genetics* (2018): 1.
- Engineering of CRISPR-Cas12b for human genome editing.
 - Strecker et al. *Nature Communications*. <https://doi.org/10.1038/s41467-018-08224-4> (22 January 2019).

With respect to (c), consider potential positive and negative environmental impacts of current and near-future applications of synthetic biology including those containing engineered gene drives:



Since the last meeting of the AHWG there have been few articles addressing the request described in point (c). Research continues on both gene drives and genomic modification in various systems however the majority of publications describe the technical approaches taken to effect desired outcomes. Below are three articles that address broadly the issue of environmental impacts of these technologies.

- Emerging and novel techniques for insect genomic modifications applicable to numerous applications including those with environmental impact.
Glantz, Valention M. and Akbari, Omar S. Gene editing technologies and applications for insects. *Current Opinions in Insect Science*. 2018. 28:66-72
- Innovations in genome modification in Yeast and its applications to environmental issues including bioremediation and bio-sensing.
Binbin Chen, Hui Ling Lee Yu Chyuan Heng, Niyong Chua, Wei Suong Teo, Won Jae Choi, Susanna Su Jan Leong, Jee Loon Foo, Matthew Wook Chang. Synthetic biology toolkits and applications in *Saccharomyces cerevisiae*. 2018 *Biotechnology Advances*. 36:1870-1881.
- Addressing Synthetic biology impact related to security, health and environmental issues from an American perspective however issues are applicable more broadly as well.
Carter, Sarah R. and Warner, Christopher M. Trends in Synthetic Biology Applications, Tools, Industry, and Oversight and Their Security Implications. 2018 *Health Security*. 16: 320-333.

With respect to (d), consider living organisms that may fall outside the definition of LMOs as per the Cartagena Protocol:

No examples could be found.



Annex 1

Date: 14 December 2018

From: Executive Secretary, Convention on Biological Diversity

To: CBD National Focal Points, relevant organizations, and indigenous peoples and local communities

cc: SBSTTA National Focal Points, Cartagena Protocol National Focal Points, Nagoya Protocol Focal Points

Subject: Submission of information on synthetic biology and nomination of experts to participate in the Open-ended Online Forum on Synthetic Biology

Thematic area: Convention on Biological Diversity

Access to Genetic Resources and Benefit-sharing

Cartagena Protocol on Biosafety

Ref.: SCBD/CP/DC/MA/MW/87791

NOTIFICATION

No. 2018-103

Dear Madam/Sir,

In decision 14/19, the Conference of the Parties to the Convention on Biological Diversity recognized that synthetic biology is rapidly developing and a cross-cutting issue, with potential benefits and potential adverse effects vis-à-vis the three objectives of the Convention on Biological Diversity, and agreed that broad and regular horizon scanning, monitoring and assessing of the most recent technological developments is needed.

The Conference of the Parties decided to extend the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology with renewed membership, taking into account, inter alia, the work on risk assessment under the Cartagena Protocol, to work in accordance with the terms of reference annexed to the decision.

The Conference of the Parties also decided to extend the Open-ended Online Forum on Synthetic Biology, taking into account the work on risk assessment under the Cartagena Protocol, to support the deliberations of the AHTEG on Synthetic Biology, and invites Parties, other Governments, indigenous peoples and local communities and relevant organizations to continue to nominate experts to take part in the Online Forum on Synthetic Biology.

Further in the same decision, the Conference of the Parties invited 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;



(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;

(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; and

(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.

The various elements of the decision will be carried out in a systematic manner, through a continuous process comprising: (i) submission of information on synthetic biology; (ii) discussions through the open-ended online forum (tentatively to be held in March 2019); (iii) one face-to-face meeting of the AHTEG (tentatively to be held in June 2019); and (iv) peer-review of the outcomes of the AHTEG. The outcomes of this process will be submitted for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) at its twenty-fourth meeting to be held in 2020.

Accordingly, at this stage, I am pleased to invite Parties, other Governments, relevant organizations and indigenous people and local communities to:

(a) Submit to the Secretariat (secretariat@cbd.int) information and supporting documentation on the four topics referred to above as soon as possible, but no later than **15 February 2019**. Submissions from Parties should be made through the Focal Points of the Convention on Biological Diversity. In the case of organizations, information should be submitted through the head of such organization. The information submitted will be made available for consideration by the online forum and the AHTEG on Synthetic Biology; and

(b) To nominate experts to participate in the Open-ended Online Forum on Synthetic Biology. CBD National Focal Points or Heads of organizations, as appropriate, are kindly requested to submit nominations for experts via e-mail to secretariat@cbd.int clearly indicating the names and e-mails of each nominee. Nominees will be subsequently contacted by the Secretariat to facilitate their registration in the Open-ended Online Forum by completing an online form outlining their experience in the field of synthetic biology. The Online Forum is open to all interested participants but they must be registered in order to contribute to the online discussions. The outcomes of the online discussions will serve as a basis for the deliberations by the AHTEG on Synthetic Biology. Nominations of experts to the Open-ended Online Forum on Synthetic Biology must be received before **15 February 2019**.

The text of this notification is also available on the CBD website at:

<http://www.cbd.int/doc/notifications/2018/ntf-2018-103-synthetic-biology-en.pdf>



Please accept, Madam/Sir, the assurances of my highest consideration.

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