**SYNTHESIS OF VIEWS IN RESPONSE TO PARAGRAPH 10 of
DECISION XIII/17 ON SYNTHETIC BIOLOGY**

1. In response to paragraph 10 of decision XIII/17, the Executive Secretary issued a notification on 16 March 2017 inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information and supporting documentation on the six topics referred to in the decision.
2. A total of 29 submissions were received by the Secretariat. Among the submissions, 15 were from Parties, 1 from a non-Party, and 13 from organizations.[[1]](#footnote-1)
3. Furthermore, several submissions cited or included electronic copies of documents which have already been published elsewhere. A list of such documents is annexed hereto.
4. **Research, cooperation and activities**
5. In describing their involvement in research, cooperation and activities most Parties indicated that they support the undertaking of research on synthetic biology in their countries and in some cases do so through the provision of funds to the relevant research groups. One Party also indicated that it has a database on synthetic biology projects that are being carried out in its country[[2]](#footnote-2).
6. Several described the existence of specialised scientific committees, panels and advisory boards that focus on multidisciplinary research on various aspects of synthetic biology. The submissions indicated that these panels are not only involved in the assessing the scientific and technical impacts of synthetic biology but are also mandated to research social, ethical, regulatory, and legal issues related to synthetic biology.
7. In addition, Parties are also involved, through the aforementioned committees, in holding awareness-raising activities, such as publishing reports, information notes and hosting and participating in seminars in order to encourage public and multi-stakeholder dialogues on the potential benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity.
8. In contrast, other Parties indicated that they have limited or no capacity to carry out synthetic biology research. However, some indicated that they continue to make an effort to stay abreast of developments that occur in the field of synthetic biology through regional cooperation and participation in trainings and workshops focusing on synthetic biology.
9. **Evidence of benefits and adverse effects of synthetic biology**
10. Some submissions acknowledged that synthetic biology is a further development and new dimension of modern biotechnology. They also noted that many of the applications of synthetic biology aim at developing efficient and effective ways to respond to challenges associated with bioenergy, agriculture, health and chemical production, amongst other applications. They also listed some of the corresponding potential adverse effects that may come with the use of synthetic biology such as invasiveness, persistence, unintentional introduction into the environment and the potential of altering natural populations.
11. However, some submissions also indicated that they do not have specific evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention, noting that the benefits and adverse effects of synthetic biology are to be considered on a case-by-case basis using robust risk assessment methodology and implementing sound risk management procedures.
12. **Experiences in conducting risk assessments of organisms, components and products of synthetic biology**
13. In describing their 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, several Parties pointed to their existing risk assessment methodologies that have been in place and successfully applied in conducting risk assessments of living modified organisms for several years.
14. They also indicated that as organisms become more complex with advances in modern biotechnology, adaptations have been made to their exiting risk assessment frameworks in order to perform an adequate risk assessment. They also highlighted that in the event a risk assessment of an organism developed through synthetic biology is conducted that similar adaptations can be applied in order to obtain a methodology that satisfies the requirements posed by the organism at hand given the case-by-case nature of risk assessments.
15. Other submissions, however, highlighted that given that there are specific challenges posed by synthetic biology, existing risk assessment methodologies are inadequate when applied to the risk assessment of organisms developed through synthetic biology. Some of the gaps identified include the absence of suitable comparators, the presence of multiple modifications which may interact in unknown ways resulting in unexpected outcomes and that the accelerated rate of developing organisms using synthetic biology all of which pose challenges to regulatory systems in implementing current risk assessment methodologies. As such, there may be a need for additional research and the development of revised risk assessment frameworks to address these gaps.
16. **Examples of risk management and other measures**
17. With regards to 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, some Parties listed several avenues through which this is being achieved, as follows.
18. With respect to LMOs that that are intended for release into the environment some countries indicated that their existing biosafety legislations, which also apply to organisms developed through synthetic biology, establish specific conditions which must be met and approved by the competent national authorities prior to the release of any such organisms. In addition, a monitoring plan should be put in place prior to the release. Furthermore, monitoring plans may include inspection measures and the use of testing methods to detect unauthorized LMOs that have been released into the environment.
19. With regards to organisms developed through synthetic biology that are intended for contained use, some countries indicated that their existing biosafety legislations set out specific containment guidelines for LMOs. These guidelines outline the varying levels of containment that are required when handling different types of LMOs and what measures are to be put in place when doing so.
20. **Regulations, policies and guidelines**
21. When describing regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology, several submissions noted that their existing biosafety laws for regulating LMOs have been in place and successfully applied for several years. They also explained that within their national frameworks, the biosafety laws also extend to organisms developed through synthetic biology and that there is no specific legislation for synthetic biology.
22. Parties also reiterated the importance, under such regulations, of conducting risk assessments of any LMO or organism developed through synthetic biology on a case-by-case basis.
23. Regarding products of synthetic biology, in their submissions some Parties indicated that other regulations and instruments are already in place that provide the necessary risk assessment frameworks.
24. No guidelines focusing specifically on synthetic biology, either in place or under development, were mentioned in the submissions.
25. **Knowledge, experience and perspectives of indigenous peoples and local communities**
26. In discussing the 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, Parties stressed importance of indigenous peoples and local communities being actively involved in the different deliberations on synthetic biology under the Convention and its Protocols.
27. In their submissions, Parties indicated that their existing biosafety frameworks, which they also apply to organisms developed through synthetic biology, have provisions for public participation, including specific provisions for consulting indigenous peoples and local communities. Such consultations take place through various means including having a specific liaison to work closely with them where activities may have applications or implications for the natural environment.
28. One Party also noted the importance of having the Ad Hoc Technical Expert Group on Socioeconomic Considerations under the Cartagena Protocol analyse the impact of synthetic biology on “productive chains of socio-biodiversity”.

**Annex 1**

**List of documents CITED OR INCLUDED as electronic copies IN THE submissions**

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| **Title** | **Submitted by** |
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1. The notification and submissions are available online at <http://bch.cbd.int/synbio/submissions/2017-2018.shtml>. [↑](#footnote-ref-1)
2. http://www.biosintetica.mx/ [↑](#footnote-ref-2)