

UPDATED BRIEFING NOTE FOR CBD COP-15
Third World Network, November 2022

Item 27: Synthetic biology

Status

At the resumed SBSTTA-24 meeting in Geneva in March 2022, there was no time to discuss the L-doc on synthetic biology, which arose from the first part of SBSTTA-24 held online. The SBSTTA recommendation for synthetic biology (CBD/SBSTTA/REC/24/4) therefore was adopted with numerous square brackets (indicating disagreement) that will need to be resolved at COP-15 (see the compilation of draft decisions in CBD/COP/15/2). A Contact Group is expected to be established to further the discussions.

Key issues

1. *Preambular paragraph relating to gene drives and the precautionary approach*

Current text: [*Recalling paragraphs 9 to 11 of decision 14/19, and calling upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention*]

Proposal: **The square brackets should be removed and the text retained.**

Rationale:

- The discussions on synthetic biology continue to be relevant and applicable to the controversial issue of organisms containing engineered gene drives. A precautionary approach is warranted given the many uncertainties and potential for widespread adverse effects beyond national boundaries.
- Paragraphs 9 to 11 of decision 14/19 laid down strict and precautionary conditions for any introduction of organisms containing engineered gene drives into the environment, including for experimental releases and for research and development purposes.

2. *Whether synthetic biology is a new and emerging issue*

Current text (Para 2): *Also recognizes that decisions X/13, XI/11, XII/24, XIII/17 and 14/19 mandated work on synthetic biology under the Convention, and that the results of the application of the criteria as set out in decision IX/29 to the issue of synthetic biology have been inconclusive in determining whether synthetic biology is a new and emerging issue or not [and decides not to require further analysis on whether synthetic biology is a new and emerging issue] [while keeping the Convention's work on synthetic biology under review][recognizing that synthetic biology has not been determined to be [or not to be] a new and emerging issue]*

Proposal: *Also recognizes* that decisions X/13, XI/11, XII/24, XIII/17 and 14/19 mandated work on synthetic biology under the Convention, and that the results of the application of the criteria as set out in decision IX/29 to the issue of synthetic biology have been inconclusive in determining whether synthetic biology is a new and emerging issue or not ~~{and decides not to require further analysis on whether synthetic biology is a new and emerging issue}~~ ~~{while keeping the Convention's work on synthetic biology under review}~~ ~~{recognizing that synthetic biology has not been determined to be [or not to be] a new and emerging issue}~~

Rationale:

- The lack of consensus on whether synthetic biology is considered a “new and emerging issue” under the Convention has caused some Parties to oppose a board and regular horizon scanning, monitoring and assessment process of the most recent technological developments, even though it had already been agreed in Decision 14/19 that such a process is needed.
- Since there already has been serious work under the CBD on synthetic biology for many years, and many Parties are of the view that the horizon scanning, monitoring and assessment process should be established and implemented without delay, it is time to move on from debating whether or not it is a “new and emerging” issue.

3. *Horizon scanning, monitoring and assessment process*

3.1 Time period

Current text (Para 4): *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in section A of the annex; [and for an [initial] [period of] [two cycles during two consecutive intersessional periods;] [one intersessional period;]]]

Proposal: *Establishes* a process for broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology as set out in section A of the annex; ~~{and for an {initial} {period of} {two cycles during two consecutive intersessional periods;}} {one intersessional period;}}]~~

Rationale:

- A major point of contention is the period of time the horizon scanning, monitoring and assessment process should be carried out for. There was also disagreement as to whether or not to extend this initial process once it has completed.
- The continuing need for the process is expected to be assessed in light of the overall assessment of the effectiveness of the process. Therefore, a review has been built in (see para 9(d)); however, there is no consensus yet on how often this should happen, as that is dependent on how long the Parties decide to establish the process for.

- It would be prudent to establish the process for at least two intersessional periods so that adequate work can be carried out and is not limited by lack of time. A horizon scanning, monitoring and assessment process ideally needs to be consistent to keep pace with the fast-moving developments in synthetic biology.

3.2 Responsible body and scope

Current text (Para 5): [*Establishes a multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment in accordance with the terms of reference contained in section B of the annex;*]

Proposal: **The square brackets should be removed and the text retained, with the addition of the text in bold:** ~~[Establishes a multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to support the process for broad and regular horizon scanning, monitoring and assessment~~ **of the organisms, components and products of synthetic biology** ~~in accordance with the terms of reference contained in section B of the annex;]~~

Rationale:

- There is disagreement as to what body should carry out the horizon scanning, monitoring and assessment process. Some Parties wanted a “multidisciplinary Ad Hoc Technical Expert Group”, while others felt this was a task for SBSTTA.
- Text referring to the multidisciplinary AHTEG is therefore all in square brackets, including the terms of reference for the group. Text referring to SBSTTA carrying out the process is presented as an alternative.
- It would be better for a multidisciplinary AHTEG to be established, so as not to overburden SBSTTA. Further, this is a specialist task that would be better suited for a smaller, balanced group with the necessary expertise.
- The issue of multidisciplinary is important to incorporate the expertise needed to cover the increasing diversity of applications that are rapidly expanding in different fields, and to fully take into account human, animal and plant health, cultural and socioeconomic impacts.
- In addition, there should be clarity that the process of horizon scanning, monitoring and assessment applies to the organisms, products and components of synthetic biology. This would be in accordance with previous COP Decisions, which recognize that significant risks also arise from the components and products of synthetic biology.

4. *Annex, Part A: Process for the horizon scanning, monitoring and assessment*

4.1 Table 1

Current text (Para 2): [For each step, the coordinating actors, other actors and main considerations for the process are as set out in table 1.]

Proposal: **The square brackets should be removed and the text retained.**

The square brackets around Table 1 should also be removed.

Rationale:

- Table 1 sets out the detail on how the process for horizon scanning, monitoring and assessment should be carried out, as recommended by the AHTEG on Synthetic Biology.
- This detail needs to be retained to provide guidance to the horizon scanning, monitoring and assessment process. If not, there will be no clear tasks and the process would be devoid of meaning.

4.2 Scope of impacts

Current text (Para 3): The Subsidiary Body on Scientific, Technical and Technological Advice shall review the outcomes of the process and make recommendations on technological developments in synthetic biology and their potential positive and negative impacts for the objectives of the Convention [including social, economic and cultural impacts as well as related ethical issues].

Proposal: **The square brackets should be removed and the text retained.**

Rationale:

- Synthetic biology has wide ranging implications that are not just limited to environmental and health risks.
 - Decision XIII/17 already invited Parties to take into account, in accordance with their applicable domestic legislation or national circumstances, as appropriate, socio-economic, cultural and ethical considerations.
5. *Terms of reference for the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (Annex, Part B)*

Current status: Because Parties could not agree which body should carry out the horizon scanning, monitoring and assessment process, the terms of reference for the multidisciplinary AHTEG are bracketed in their entirety.

Proposal: **The square brackets around the TOR should be removed.**

5.1 Specific tasks

Specific tasks for the group were also not agreed upon (see Para 1 of the Annex, Part B).

- **These are all important elements for the group to carry out and the brackets around Paras 1(a), 1(c), 1(d), 1(e) and 1(f) should be lifted.**
- It should be clarified that the assessment process should take into consideration issues related to **contained use and unintentional release into the environment**. These elements can be added to Para 1(a).
- It would be important to retain reference to a **participatory assessment process** in Paras 1(a) and 1 (b), in order to ensure the full and effective

participation of indigenous peoples and local communities in the discussions and in the work on synthetic biology under the Convention, in accordance with Decision 14/19.

- It would also be important to retain reference to **other knowledge systems** in Para 1(c), as the knowledge, experiences and perspectives of indigenous peoples and local communities are important for a better understanding of synthetic biology, as acknowledged in Decision 13/17.
- In order to prevent the transfer of technologies that may pose risks to biodiversity, it would be important to link technology transfer to technology assessment. This can be done by lifting the brackets in Para 1(e) and adding the text in bold: Identify capacity-building, **technology assessment**, technology transfer and knowledge sharing needs based on priorities determined by Parties on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process.
- The tasks of **detecting, identifying and monitoring** are important for the horizon scanning, monitoring and assessment process. These have to apply *both* to the organisms, components and products of synthetic biology, and to their impacts. As such the brackets in Para 1(f) should be lifted, with the addition of the text in bold: Evaluate the availability of tools to detect, identify and monitor the organisms, components and products, **and** the potential positive and negative impacts, of synthetic biology.

Proposal:

1. The multidisciplinary Ad Hoc Technical Expert Group, building on the previous relevant work under the Convention and its Protocols, including the work of the previous Ad Hoc Technical Expert Groups on Synthetic Biology, shall:

{(a) Assess, vis-à-vis the three objectives of the Convention and its Protocols {and making use of tools and approaches to enable a participatory assessment process}, based on the results of steps in A1(a) and A1(b) above **and taking into consideration contained use and unintentional release into the environment**; (i) new technological developments and applications of synthetic biology, and (ii) state of knowledge on potential impacts on biodiversity and the environment of current and future synthetic biology applications, taking into account impacts on human, animal and plant health, and cultural and socioeconomic issues;}

(b) {Make use of tools and approaches to enable a participatory assessment process} to review and assess the information gathered through the process for broad and regular horizon scanning, monitoring and assessment and, on this basis, consider technological developments in synthetic biology and their potential positive and negative impacts {and their implications} for the objectives of the Convention;

{(c) Identify a methodology for the assessment of the compiled information, based on {scientific evidence} {best scientific knowledge and other knowledge systems}, considering the availability and accessibility of tools and expertise;}

(d) Identify trends and issues, including categories of synthetic biology that may need to be prioritized or that may need to continue to be considered in subsequent cycles, as well as additional issues that may be regarded as priorities vis-à-vis the three objectives of the Convention for the next intersessional period;

(e) Identify capacity-building, **technology assessment**, technology transfer and knowledge sharing needs based on priorities determined by Parties on issues related to synthetic biology and in the light of the outcomes of the horizon scanning process;

(f) Evaluate the availability of tools to detect, identify and monitor the organisms, components and products and potential positive and negative impacts of synthetic biology;

(g) Prepare a report on the outcomes of its assessment to be submitted to the Subsidiary Body on Scientific, Technical and Technological Advice;

(h) Make recommendations to the Subsidiary Body on Scientific, Technical and Technological Advice on specific issues that may require further consideration by the Conference of the Parties and/or the Parties to the Cartagena Protocol and the Parties to the Nagoya Protocol.

5.2 Paragraphs not yet discussed

The Contact Group at the first part of SBSTTA 24 did not discuss further paragraphs in the terms of reference related to the composition of, and applicable procedures for, the multidisciplinary AHTEG, nor was there subsequent time to do so. The following are key issues in this regard:

- Current text in Para 2 relating to **expertise from a broad range of disciplines, as well as interdisciplinary and intercultural expertise, and indigenous peoples and local communities**, should be retained. Multidisciplinarity is essential for ensuring that the full spectrum of the potential impacts of synthetic biology on biodiversity, as well as on human, animal and plant health, and cultural and socioeconomic issues are identified, assessed and monitored.
- Current text in Para 3 obligating the **application of the procedure adopted by Parties for avoiding or managing conflicts of interest in expert groups**, should be retained. This is important to ensure that the horizon scanning, monitoring assessment process is carried out in a manner that is independent, particularly because of the vested interests that some experts may have.