

Braulio Ferreira de Souza Dias Executive Secretary Secretariat of the Convention on Biological Diversity United Nations Environment Programme 413 Saint-Jacques Street, Suite 800 Montreal, Quebec, Canada H2Y 1N9

CBD Notification 2016-008: Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology

31 January 2016

Dear Ferreira de Souza Dias,

On behalf of the members of the Public Research and Regulation Initiative (PRRI) who have participated in the various discussions on Synthetic Biology under the CBD, I express our appreciation for the active role of the secretariat in the context of decision XII/24 on synthetic biology.

In response to Notification 2016-008: please find below the observations of those members on the Updated report and synthesis of views in response to paragraph 7(b) of decision XII/24; and the Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology.

UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TOPARAGRAPH 7(b) OF DECISION XII/24

A general observation is that while the input in the submissions and online discussions showed a rich and balanced diversity in terms of anticipated benefits and potential risks of the use of synthetic biology, the updated report and synthesis display a disproportionate selection of contributions that focus on risks and uncertainties, and do not take into account the comments that were made about the anticipated benefits and the knowledge and experience accumulated over the last decades.

For example: Paragraph 15. "It was noted that the objective of fair and equitable sharing of benefits arising from the use of genetic resources may lose its purpose, as use of components, organisms and products from synthetic biology may replace the need for and use of natural genetic resources. A participant in the online forum also noted that a profit-driven approach to synthetic biology does not necessarily support the fair sharing of costs and benefits between developed and developing countries, and that this situation has been exacerbated by control over the techniques of synthetic biology by a limited number of stakeholders, most of whom are driven primarily by a profit motive rather than by ecological perspective." This ignores the fact that these technologies also aim to make it more accessible for people to develop their own solutions to their needs, and there is much public research in this field, which is not profit driven. People concerned with "profit motives" may not be considering the products that could be developed (already are) by public research institutions (EMBRAPA,CINVESTAV etc), universities, small companies (Oxitec) or non-profit organizations (Golden Rice Project).



Example: Paragraph 17: "It was also noted that a lack of scientific underpinning to ecological and social impacts in the application of synthetic biology processes poses a key issue in the discussion on the relationship between synthetic biology and biodiversity. An increase in the complexity and range of synthetic biology tools and techniques may also lead to an increase in the uncertainty and unpredictability of their outcomes, making it harder to predict their effects on biodiversity, leading tithe need for stricter measures to prevent damage to biodiversity.

Example: Paragraph 21: "There were also participants who noted that it is premature to discuss the relationship between synthetic biology and biodiversity since an agreement has not been reached on whether or not synthetic biology is a new and emerging issue for conservation and sustainable use of biodiversity. Furthermore, some participants also noted that since no one fully understands the risks posed by synthetic organisms to the environment, there are challenges as to what kinds of information is needed to support rigorous risk assessments, or who should collect such data."

Many participants on the on-line forum, especially those with wide experience on biotechnology and synthetic biology developments, commented that **the** basic principles of an Environmental Risk Assessment can be applied to products of synthetic biology. This is not reflected on Paragraph 21.

Example Paragraph 26: (a) The differences between an LMO and an organism developed through synthetic biology **lie mainly on the higher level of complexity of the latter**. Such complexity may result from the combination of several techniques of genetic engineering to produce an organism combined with other techniques that rely on the standardization and abstraction of modular biological components. Furthermore, LMOs are organisms developed by incorporating a single or a few gene(s) of interest, whereas organisms constructed by means of synthetic biology techniques are **likely** to have larger segments of modified DNA or even complete novel genomes". The statements in bold are not substantiated and in fact incorrect. Several participants have underlined that one of the aims of SynBio is to decrease complexity, which is not reflected in the report.

Example Paragraph 26 (c) The production of living organisms through modern biotechnology and synthetic biology is similar but the genes and nucleic acid molecules transferred into the recipient organisms differ in that nucleic acids transferred through modern biotechnology **exist in nature but not those transferred through..."**. As was brought forward in the discussions, it makes no difference whether the DNA was taken from an organism or synthesized.

REPORT OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY.

The report is a good reflection of the AHTEG discussions.

Some observations in relation to "the way forward":

- Complement for the benefit of SBSTTA the proposed operational definition with a large variety of examples of current Synbio applications.
- The existing regulatory systems an risk assessment mechanisms are adequate for the near and medium term future applications of Synbio. Continuous monitoring of SynBio developments is important.



- Take into consideration the work of the Organization for Economic Cooperation and Development in this field.
- Use the online platform of the BCH facilitates for exchanges of scientific information, experiences and views.

Yours Sincerely

Em. Prof. Marc baron Van Montagu,

Chairman of the Public Research and Regulation Initiative (PRRI)

World Food Prize Laureate 2013

3