**comments on the report of the Ad Hoc Technical Expert Group on Synthetic Biology BY the german central committee on biological safety**

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| **Title of document reviewed:** | **REPORT OF THE ADHOC TECHNICAL EXPERTGROUP ON SYNTHETIC BIOLOGY CBD/SYNBIO/AHTEG/2017/1/3** |
| **Comments on the draft documentation for SBSTTA-22:** |
| **Page #** | **Para #** | **Comment** |
| 0 | 0 | The German Central Committee on Biological Safety (ZKBS) has been carrying out a continuous monitoring of synthetic biology activities[[1]](#footnote-1) since 2009 as suggested in both reports of the AHTEG on Synthetic Biology. Throughout this monitoring, the **ZKBS has not identified any living organism developed through synthetic biology that cannot be regarded as a living modified organism (LMO)** as per the Cartagena Protocol on Biosafety. The ZKBS therefore considers the operational definition established by the AHTEG as too broad. It does not allow to discriminate between LMOs as defined by the Cartagena Protocol and living organisms developed through synthetic biology that may need further consideration with a view to the three objectives of the Convention on Biological Diversity. This point should be emphasized since among the original Terms of Reference of the AHTEG (Decision CDB XII/24) was the task “*to determine if living modified organisms derived from synthetic biology fall under the scope of the Cartagena Protocol*”[[2]](#footnote-2).  |
|  |  | Scrutiny reservation against the broad conception of the operational definition was previously expressed by the ZKBS[[3]](#footnote-3) and SBSTTA 20[[4]](#footnote-4). Inclusion and exclusion criteria should be determined.  |
|  |  | The ZKBS suggests that no type of LMO should be considered for review by the AHTEG on Synthetic Biology as these can be handled under the Cartagena Protocol. **The AHTEG should rather focus on living organisms developed by synthetic biology that bear significant novelties and which are not LMOs as defined by the Cartagena Protocol.** |
|  |  | In consequence to the AHTEG’s too unspecific definition of Synthetic Biology, several established tools of modern biotechnology resulting in LMOs as defined by the Cartagena Protocol are assigned incorrectly to the field of Synthetic Biology. This relates to the following technological developments:  |
| 3 | 15 | Paragraph 15 * (c) and (e): **gene editing tools** and their use in established laboratories as well as in **DIY biology** are classical methods of modern biotechnology.
* (d): organisms containing **engineered gene drives** possess a novel combination of genetic material obtained through the use of modern biotechnology and are thus LMOs.
* (i): **modified algae** used for the production of chemical substances are LMOs that can be easily kept in contained facilities (bioreactors passable for sunlight or powered through artificial light sources).
* (k): **RNA interference** has been used for a long time as a tool of modern biotechnology.
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| 5 | 27, 28, 30, 44, 41 (d), 51 | The ZKBS agrees with the conclusion of the AHTEG that “living organisms already developed or currently under research and development through techniques” identified as synthetic biology by the AHTEG, “including organisms containing **engineered gene drives,** fell under the definition of LMOs as per the Cartagena Protocol”. This conclusion should also be extended to chapter 3.5, where gene drives are specifically addressed. The ZKBS has issued a general position statement on the production and use of organisms using recombinant gene drive systems[[5]](#footnote-5) in which it concludes that these can be assessed for their safety using national regulations (German Genetic Engineering Act and Genetic Engineering Safety Regulations). The national position statement on engineered gene drives has recently been internationally proposed to the scientific public[[6]](#footnote-6).The ZKBS does not consider **epigenetics** as a technique of genetic modification as these do not result in a novel combination of genetic material. |
| 6 | 33 | The ZKBS points out that an organism indistinguishable from a naturally occurring or conventionally bred counterpart does not pose any risk other than that posed by organisms resulting from natural variation. The development of additional detection, identification and monitoring tools is considered as unnecessary. Those organisms should be treated equally as their naturally occurring or conventionally bred counterparts. |
| 6 | 34-38 | The ZKBS does not see a general need for specific detection and monitoring instruments of current products of synthetic biology. A chemical substance will not behave differently in the environment whether it is produced with the help of chemical synthesis or with an organism developed through synthetic biology. |
| 7 | 48 | The ZKBS recommends to continue monitoring activities in the field of synthetic biology to identify and focus on those organisms that do not fall within the scope of the Cartagena Protocol and might need further consideration with regard to the three objectives of the Convention on Biological Diversity.  |

1. Monitoring of Synthetic Biology in Germany 1st Interim report of the Central Committee on Biological Safety; [https://www.zkbs-online.de/ZKBS/SharedDocs/Downloads/02\_Allgemeine\_Stellungnahmen\_englisch/01\_general\_subjects/1st%20Monitoring%20SynBio%20(2012).pdf?\_\_blob=publicationFile&v=3](https://www.zkbs-online.de/ZKBS/SharedDocs/Downloads/02_Allgemeine_Stellungnahmen_englisch/01_general_subjects/1st%20Monitoring%20SynBio%20%282012%29.pdf?__blob=publicationFile&v=3); BCH Record Id # 110828; <https://bch.cbd.int/database/record.shtml?documentid=110828> [↑](#footnote-ref-1)
2. Decision XII/24 – New and emerging issues: synthetic biology (UNEP/CBD/COP/DEC/XII/24); <https://www.cbd.int/decisions/cop/?m=cop-12> [↑](#footnote-ref-2)
3. General position statement of the ZKBS on the “Report of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology” from 7 October 2015 (ZKBS (b)) in BCH Record Id #109733; <https://bch.cbd.int/database/record.shtml?documentid=109733> [↑](#footnote-ref-3)
4. Report of the Subsidiary Body on Scientific, Technical and Technological Advice on its twentieth Meeting (UNEP/CBD/SBSTTA/20/16); <https://www.cbd.int/meetings/SBSTTA-20> [↑](#footnote-ref-4)
5. General position statement of the ZKBS on the classification of genetic engineering operations for the production and use of higher organisms using recombinant gene drive systems, [45310.0111\_EN\_GeneDrive.pdf](http://bch.cbd.int/database/attachment/?id=16811) in BCH Record Id # 110745; <https://bch.cbd.int/database/record.shtml?documentid=110745> [↑](#footnote-ref-5)
6. Strassheim S & Schenkel W (2018). Existing rules cover gene-drive applications. *Nature* 554(7691):169-169. [↑](#footnote-ref-6)