Berlin, 15 February 2016

**Comment of the ZKBS to the “Updated report and synthesis of views in response to paragraph 7(b) of decision XII/24 on new and emerging issues: synthetic biology” from 4 September 2015**

Prof. Dr. Uwe Sonnewald as a member of the German Central Committee on Biological Safety (ZKBS) and Dr. Swantje Straßheim as a member of the Committee´s scientific office have participated in the online forum on synthetic biology convened by the Convention. The ZKBS has been informed about the discussions and conclusions of the online forum and would like to emphasize some points and add further points to the note published by the executive Secretary (UNEP/CBD/SYNBIO/AHTEG/2015/1/2).

Concerning II. Relationship between synthetic biology and biological diversity

The note by the Executive Secretary states under point 20. that some participants found it challenging to discuss a relationship between synthetic biology and biological diversity in the absence of an operational definition of synthetic biology It should be added to this point that many participants also stated that organisms produced by applications of synthetic biology are LMOs as defined in the Cartagena Protocol (for example [#6878], [#6830] or [#6818]) and that synthetic biology should not be used as a way to revisit the general LMO case (for example [#7139]).

Concerning III. Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques

As listed under point 24. it was noted in the online forum that “components” and “products” of synthetic biology are non-living, have more in common with chemical substances, and should not be compared with LMOs.

The ZKBS suggests adding the following to this point: some participants stated that “components” standardly used in genetic engineering such as plasmids or oligonucleotides should not be included into a discussion of the effects of synthetic biology on biological diversity. They argued that those “components” are inert chemicals regulated as commercial biological products for the laboratory use and are not intended to fall under the Convention and its Protocols (see posts [#6906] and [#6942]).

Concerning IV. Operational definition of synthetic biology, comprising inclusion and exclusion criteria

The ZKBS asserts that one point made by many participants under this topic has not been summarized in the note by the Executive Secretary. Under point 29. the note states that a majority of participants “recognized the need for a definition […] which is sufficiently broad to include new developments in the field of synthetic biology”. However, one point made by many participants has not been added here. These participants were of the opinion that instead of or in addition to a definition it might be more productive to identify cases where an organism produced with synthetic biology is not an LMO (see for example posts [#6819], [#6841], [#6890] or [#7136]). Some participants also noted that the discussion about synthetic biology should not include techniques of modern biotechnology that have been used for many years and are not new nor embedded in synthetic biology. Examples given for these techniques/applications include RNAi, protein engineering, nucleic acid engineering or CRISPR/Cas (see posts [#6836], [#6997], [#6950] and [#7138]). Due to the potential to influence a range of disciplines and regulatory frameworks, one participant also advised not to use the operational definition for regulatory purposes ([#7058]).

Concerning V. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the convention and its protocols

The note by the Executive Secretary states that most participants of the online forum expect the organisms, components and products of synthetic biology to produce similar impacts as organisms resulting from classical genetic engineering. This synthesis is correct, however, it should also be noted that many, if not most of the participants of the online forum were of the opinion that the question about potential risks and benefits could not be answered in a generic way. This group of participants favored a case-by-case approach (as already implemented in LMO regulation) for each application to identify individual risks (for example, see posts [#7208], [#7205] and [#7202]). Some participants supporting this view also claimed that the risks and benefits of synthetic biology applications were closely linked to the intended use (for example contained use, field release or gene therapy) of the synthetic biology products, ([#7208] or [#7218].

Concerning IX. Outlook and possible elements of a way forward

One of the conclusions given in the outlook under (c) states that “an environmental and commercial release of organisms resulting from synthetic biology must not be performed until procedures and regulatory processes or international regulatory frameworks are in place to ensure the protection of ecological systems”. We do not agree with this conclusion when it comes to living organisms produced through synthetic biology that are considered as LMOs. If an organism produced through synthetic biology is comparable to an LMO, we can see no reason why an environmental and/or commercial release of this organism could not be performed under the current LMO regulations.