Republic of Bulgaria
MINISTRY OF ENVIRONMENT AND WATER

16 June 2017

Министерство на околната среда и водите
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Dr Cristiana Paşca Palmer
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, QC, H2Y 1N9 Canada

Subject: Reply of Bulgarian Ministry of Environment and Water to **Notification 2017-025**

Ref.: SCBD/SPS/DC/DA/MW/86375

Dear Dr Paşca Palmer,

Bulgarian experience in the area of synthetic biology research is relatively limited. Such research in Bulgaria is related to RNA engineering and design of RNA switches. All activities are carried out in contained use conditions with the lowest class of protection measures because the risks are considered low to negligible. No specific national regulations and guidelines regarding synthetic biology have been developed and general GMO legislation is applicable.

Regarding the future work on synthetic biology under the Convention on Biological Diversity, we believe two topics should be prioritised:

First, the definition of synthetic biology should be improved. At present it is too broad and this leads to some confusion. It should allow better distinction of the engineering (synthetic biology) techniques (e.g. metabolic and pathway engineering, xenobiology, protein and nucleic acid engineering, minimal cells, synthetic genomics, etc.) from the enabling technologies (e.g. next-generation sequencing, gene synthesis, gene editing, bioinformatics dealing with massive data, etc.) which are applicable to a much broader field. The key distinguishing characteristic of synthetic biology should be emphasised, namely that organisms developed through synthetic biology contain or consist of functionally important components (proteins, nucleic acids, lipids, metabolites, etc.) or processes (metabolic or signal transduction pathways, gene circuits, etc.) that do not exist in nature or are significantly different from those that exist in nature.

Second, further consideration should be given to the important aspects relevant for the risk assessment of organisms developed through synthetic biology. Those are the possible absence of suitable comparators due to the presence of non-natural components and process; multiple modifications which may interact in various ways and result in unexpected outcomes; and increase speed of generation of new organisms which may overburden the risk assessment system.

Regarding nomination of national experts for the Open-ended On-line Forum, we maintain our support for continuous participation of

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Mr Tzvetkov is currently participant in the Forum and member of AHTEG on Synthetic Biology.

Yours sincerely,

KRASIMIR ZHIVKOV

DEPUTY MINISTER OF ENVIRONMENT AND WATER