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Information to contribute to the work of the AHTEG on Synthetic Biology

Answering the question (a), all the criteria specified in Decision IX/29, paragraph 12 fully correspond to the LMOs developed using gene drive technologies and some CRISPR-Cas technologies that imply the insertion of a new sequence.

In the Republic of Belarus, at present, Synbio organisms that fall under the definition developed by the AHTEG group on synthetic biology have not been released into the environment.

At the same time, there is an interest in development by using genome editing techniques, including CRISPR/Cas9 and some new techniques. Some applications have been submitted to State Scientific Programs for the implementation of such scientific projects, e.g. development of new model plants by using CRISPR-Cas. The country's interest in such technologies is quite high and across the globe as well. It can be assumed that the number of submitted projects will increase within a few years.

There is also a growing interest in whether the risk assessment of such organisms differs and how much their positive and negative effects on the environment are, including human health, and socio-economic impacts. In recent years, related discussions have been held both at individual organizations, for example, the National Academy of Sciences, and interdepartmental councils, for example, joint deliberations of the Ministry of Environment, the Ministry of Health, and the Academy of Sciences. What organisms should be considered as Synbio was paid a special interest to since LMOs fall under the scope of current regulations. It was concluded that, at present, all organisms that fall under the definition of the Belarusian Law 96-3 "On Safety in Genetic Engineering Activities" shall be classified as LMOs (term "genetically engineered organisms" in the Belarusian Law).

¹ "Genetically engineered organism" (genetically changed (modified, transgenic) organism) means a living organism containing a new combination of (убран артикль) genetic material produced by genetic engineering;

"Genetic engineering" means the technology for producing new combinations of (убран артикль) genetic material by means of extracellular manipulations with nucleic acid molecules and transfer of designed gene constructions into a living organism as a result of which their incorporation and activity are achieved in this organism and in its progeny.

The second conclusion is based on the discussion of new world developments published in scientific papers – not only risk assessment, but also legislative measures should be applied to some new organisms, e.g. the LMOs developed by the gene drive

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technology, and a new strong monitoring methodology and monitoring techniques should be developed for gene drive organisms.

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