Republic of Bulgaria
MINISTRY OF ENVIRONMENT AND WATER

Ref. No 99-00-96/10.08.2017

Dr Cristiana Paşca Palmer
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Subject: Reply of Bulgarian Ministry of Environment and Water to **Notification 2017-035**

Ref.: SCBD/SPS/DC/MPM/KG/MW/86376

Dear Dr Paşca Palmer,

Bulgarian Ministry of Environment and Water, National Competent Authority under the Cartagena Protocol on Biosafety has the following comments on the issues addressed by Notification 2017-035:

1. Criteria for selection of topics for the development of further guidance on specific topics of risk assessment of LMOs

We fully support the Criteria for selection of topics for development of Guidance(s) on Risk Assessment of Living Modified Organisms (LMO) proposed in the reply to Notification 2017-035 submitted on behalf of EU and its Member States. We believe that those criteria will allow the resources (human capacity, finances and time) available under Cartagena Protocol on Biosafety to be utilised in the most efficient way to further the objectives of the Protocol. Accordingly Section C of the Annexed Form is identical to the one in that reply.

2. Proposal for initiation of work on further Guidance on Risk Assessment of LMO carrying Gene Drives

Gene drive is often understood as a practical implementation of the concept that there are mechanisms that allow genetic structure of populations to be changed faster and more efficiently than it can be achieved by relying on Mendelian inheritance only (for recent review on gene drives see Champer *et al.* 2016). That concept itself is not new but only recently the technical developments, in particular those related to gene editing, have made its application practically feasible.

By their very nature gene drives could have effects on the conservation of biological diversity, because an effective gene drive would change that genetic structure of populations relatively

fast and efficiently. The effects of that changes can be beneficial (e.g. eradication of invasive alien species, making organisms unsusceptible to pathogens, etc.) or harmful (e.g. uncontrolled spread of the drive and eradication of non-target population of target species or of non-target species, removal of food base for non-target organisms, etc.) and their scale will vary depending on the particular populations and organisms targeted. Majority gene drive systems currently considered involve creation of LMO (those utilizing naturally occurring inheritable microorganisms, such as *Wolbachia* or balanced chromosomal translocation might be exceptions) and thus fall under the scope of the Cartagena Protocol. It is also notable that once released into the environment the organisms containing gene drives are expect to be very hard to control or remove and can affect biological diversity beyond national boundaries or the populations originally targeted.

Development of gene editing techniques (e.g. Cas9-CRISPR) holds a great promise that finally efficient and effective gene drive systems will be available both for scientific research and for commercial purposes.

Gene drives in principle can be introduced into any sexually reproducing organism and to be based on different biological processes. Despite of that main sources of risk for the environment are pretty general and in most cases during risk assessment same key variables should be considered, e. g. efficiency of conversion in wild populations, effective size of the populations, generation times, presence of reproduction compatible non-target species, geographic or other isolation from other non-target population of the same species, etc. This justifies the development of general guidance document covering risk assessment of various gene drive systems.

To the best of our knowledge no guidance documents which specifically address risk assessment of organisms that contain gene drives are available at present.

In conclusion, taking into account the above considerations we believe that possibility for development under the Cartagena Protocol of Guidelines document on risk assessment of organisms that contain gene drives should be given a serious consideration at COP-MOP 9. The necessity of broad (international) cooperation when assessing the risks for the environment from gene drives in order to realise their potential benefits while adequately managing the risks has been noted by the leading scientists in the field, learned societies, national political bodies and scientific advisory committees (e.g. Akbari et al. 2015; NASEM, 2016; Norwegian Biotechnology Board Statement 2017; UK House of Lords Report 2015). If a process for development of Guidelines document on risk assessment of organisms that contain gene drives is initiated under the Cartagena Protocol, it will be very beneficial to develop through the CBD Secretariat at an early stage close cooperation with other international or national bodies addressing other aspects of the risks posed by such organisms, e.g. effects on human health, laboratory and occupational safety, security implications, etc.

3. Perceived gaps in existing guidance materials

At this stage, Bulgarian Competent Authority has identified no gaps in existing guidance.

References

Akbari, O.S., Bellen, H.J., Bier, E., Bullock, S.L., Burt, A., Church, G.M., Cook, K.R., Duchek, P., Edwards, O.R., Esvelt, K.M. and Gantz, V.M., 2015. Safeguarding gene drive experiments in the laboratory. *Science*, *349*(6251), pp.927-929.

Champer, J., Buchman, A. and Akbari, O.S., 2016. Cheating evolution: engineering gene drives to manipulate the fate of wild populations. *Nature reviews. Genetics*, *17*(3), pp.146-159.

National Academies of Sciences, Engineering, and Medicine, 2016. Gene drives on the horizon: advancing science, navigating uncertainty, and aligning research with public values. National Academies Press.

The Norwegian Biotechnology Advisory Statement on Gene Drives, 2017. http://www.bioteknologiradet.no/filarkiv/2017/02/Statement-on-gene-drives.pdf

House of Lords Report on Genetically modified Insects, 2015. http://www.parliament.uk/genetically-modified-insects

Annex: Filled Form for the submission of information requested in Decision VIII/12

Yours sincerely,

KRASIMIR ZHIVKOV

DEPUTY MINISTER OF ENVIRONMENT AND WATER

Annex

FORM FOR THE SUBMISSION OF INFORMATION REQUESTED IN DECISION VIII/12 ON RISK ASSESSMENT AND RISK MANAGEMENT

A. Country information

Country name:	**Bulgaria**

B. Please indicate your country's needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs)

	Needs and priorities for further guidance on risk assessment of LMOs	**Notes**
1	**Guidance on risk assessment of organisms that contain gene drives**	• Organisms that contain gene drives by definition should have environmental effects; • Organisms that contain gene drives once released into the environment would be very hard to contain within the national borders or to be eradicated; • Recent developments, in particular those related to gene editing, might enable development of practically applicable gene drives systems in near future; • Most organisms that contain gene drives under consideration at present will be LMO; • No guidance documents that specifically address risk assessment of organisms that contain gene drives are available; • The necessity of broad (international) cooperation when assessing the risks for the environment from such organisms has been identified by the leading scientists in the field, learned societies, national political bodies and scientific advisory committees.

*C. Please propose possible criteria that may facilitate the selection of topics for the development of further guidance on specific topics of risk assessment of LMOs, including a technical justification for each of the criterion proposed**

	Criteria for the selection of topics	Notes and technical justification
1	Risk assessment with regard to the topics in question is within the scope and objectives of the Protocol	The EU and its Member States think these criteria can be helpful in selecting topics for the development of further guidance. When doing this, we recommend a structured analysis of topics along the following steps: • From the range of potential topics, select clearly defined topics that could require further guidance and are within the scope and objectives of the Protocol (see criterion 1); • Analyse available information to determine whether those topics can be covered by existing guidance (see criterion 2). This should in particular and at least involve an analysis of the applicability of the guidance that has been developed in the context of the Protocol; • When considering developing further guidance for issues for which existing guidance has been found to be insufficient, prioritise development of further guidance based on the pace of scientific advancements, the state of development of the LMO in question and the potential risks to biodiversity and human health (see criteria 2-4).
2	Risk assessment with regard to the topics in question cannot be performed by using existing guidance documents	
3	Specific topics with a high pace of scientific and technological advancement	
4	Specific topics with potential adverse effects on biodiversity and/or human health	
5	Specific topics might be prioritised if the LMOs in question are already, or are likely to be, commercialised and marketed somewhere in the world	

D. Please share your views on perceived gaps in existing guidance materials

	Perceived gaps
	At this stage, we have identified no gaps in existing guidance.