



REPUBLIC OF BULGARIA
MINISTRY OF ENVIRONMENT AND WATER

Ref No 99-00-79 / 15.03 2019

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 2019-009**

Reference: SCBD/CPU/DC/MA/MW/87798

Dear Dr Paşca Palmer,

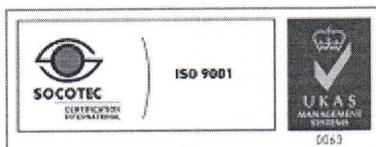
The Bulgarian Ministry of Environment and Water want to provide the following information relevant to the work of the on-line forum and the AHTEG and requested by the Notification:

a) Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so;

Bulgaria so far has not performed risk assessment of living modified organisms containing engineered gene drives and of living modified fish.

b) Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish;

We consider that undertaking risk assessment of living modified organisms containing engineered gene drives will follow the established principles for risk assessment of living modified organisms. The risk assessment will have to take into account the spatial and temporal structure of the population; the genetic structure of the population with respect to the locus where the gene drive incorporates and to the target locus of any cargo, incl. the possibility to develop resistance; the effective size of the population and its interactions with other populations of the same species (e.g. migration, cross-breeding); the modes of



Sofia 1000, 22 Maria Louiza Blvd

Phone: +359(2) 940 6123, Fax:+359(2) 9406127



reproduction. This information, together with the data from limited releases or laboratory populations will have to be used to develop model(s) of the spread (in time and in space) of the gene drive in the population and/or changes in population size caused by the drive. Adequate models might be challenging to develop, especially if some of the data above is missing.

It will be important to use data about ecological relations of the species containing engineered gene drives. The challenge will be to identify how those relations will change with the spread of the gene drive and/or elimination of the target population. E.g. what species will substitute it in the ecosystem, as they might be more efficient disease vectors or be vectors for different pathogens; how the pathogens will evolve in response to the presence of gene drive – change in pathogenicity, switch to different vectors, etc.

It will be important implement adequate programme to monitor the spread of the gene drive and the changes in the size, genetic and demographic structure of the target population(s). The data obtained should be used to update and refine the models used in the initial risk assessment.

c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

Again we consider that undertaking risk assessment of living modified organisms containing engineered gene drives will follow the established principles for risk assessment of living modified organisms. Some specific information that will need to be obtained and considered is mentioned under point b). The models to be used will have to be evaluated under different regimes as the interactions can be complex and non-linear. Some of the organisms that are considered to be modified with engineered gene drives (e.g. mosquitos) have large populations that cover different countries. So it will be very important to establish at early point cooperation between the potentially affected parties in order to obtain the necessary information, perform risk assessment together or using methodologies that are recognised by all of them and design and implement monitoring programmes in those transboundary situations.

This submission supplements the reply to Notification 2019-009 by the European Union and its Member States but the views expressed here are only those of the Bulgarian Ministry of Environment and Water.

Please accept, Madam, the assurance of my highest consideration.

KRASIMIR ZHIVKOV 
DEPUTY MINISTER OF ENVIRONMENT AND WATER