**NL submission**

**Notification 2019-009**

**Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety**

Please find below the contribution of the Netherlands to Notification 2019-009. This contribution should be considered in addition to the joint EU submission for this notification.

1. **Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish; or else, lack of experience in doing so.**

***LMOs containing engineered gene drives***

There is not much experience with the environmental risk assessment (ERA) of LMOs containing engineered gene drives for actual environmental releases. However, there have been initiatives and discussions in order to prepare for such an ERA. Examples of outcomes of these discussions are *e.g.* a policy report of the Dutch RIVM on gene drives and risk assessment (Westra et al., 2016, <https://rivm.openrepository.com/handle/10029/596002>), a book of the National Academy of Science titled ’Gene drives on the horizon’ (2016), a report on a problem formulation workshop for mosquitoes with gene drives (Roberts et al, 2017, <https://www.ajtmh.org/content/journals/10.4269/ajtmh.16-0726>)

 and a report of a scientific working group on pathway for deployment of gene drives (James et al, 2018, <https://www.ajtmh.org/content/journals/10.4269/ajtmh.18-0083>).

***LM fish***

Quite some experience is already obtained with the ERA of LM fish such as salmon, tilapia and common carp. In Europe specific guidelines are available to assesses potential environmental risks of LM fish (<https://www.efsa.europa.eu/en/efsajournal/pub/3200>).

1. **Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish**

***LMOs containing engineered gene drives***

As indicated in the literature mentioned under a), the main challenge in the ERA of LMOs containing an engineered gene drive follows from the ability of a trait to potentially spread through a complete population, even in the absence of a fitness advantage. This scenario is mainly foreseen for fast reproducing, flying organisms such as insects, that contain a so-called ‘low threshold drive’, meaning that only a low number of released insects are necessary for spreading the trait. Effects can be potentially population-wide. This implicates that potential risks have to be assessed by experts with sufficient knowledge in population dynamics and modelling. Another challenge in the ERA of LMOs containing an engineered gene drive is foreseen in the staged approach needed for safety testing. Each LMO is tested by introducing the organism in a step-wise manner into the environment to collect the necessary data for ERA in a safe way. The bottleneck is often the first (semi-contained) environmental release, following the contained trials. This step may be challenging for LM insects in general, including insects with a gene drive, since insects are difficult to contain as compared to plants.

Whether releases of organisms with a gene drive would result in an adverse environmental effect, can only be assessed based on a case-by-case basis. This ERA takes into account aspects such as the specific trait, species, way of dissemination, type of gene drive system (low threshold, high threshold gene drive) and the receiving environment.

**LM fish**

There are no challenges foreseen in the ERA of LM fish as compared to other LMOs.

1. **Specific needs (if any) to properly undertake risks assessment of living modified organisms containing engineered gene drives**

We see no specific need that has to be fulfilled before an ERA of LMOs containing an engineered gene drive can be undertaken. An ERA has to performed on a case-by-case basis and data for ERA are to be generated in the frame of the specific applications. To perform the ERA, use can be made of existing guidance for LM insects and organisms with similar properties as organisms with a gene drive construct such as biocontrol agents, living microbial pesticides and invasive species.

As indicated above there is existing EFSA guidance for ERA of LM insects in which insects with gene drives are explicitly addressed. Other sources are the guidance on LM insects (as part of the voluntary guidance on risk assessment) under the Cartagena Protocol, as well as existing WHO guidance on LM insects.

Other sources that may be relevant for LMOs with a gene drive are the

ERA guidance for plant protection products of invasive species:

<https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en>.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107>

<https://www.efsa.europa.eu/sites/default/files/engage/180212-0.pdf>