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Secretariat to the
Convention on Biological Diversity

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**Subject: CBD Notification 2019-009, Risk Assessment and Risk Management under the Cartagena Protocol, Submission by Austria**

Dear colleagues,

Complementing the joint submission by the EU and its Member States Austria would like to submit the following information. We are focusing on gene drives as currently we do not have experience in LM fish.

**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;**

Currently, we are not aware of any engineered gene drive organisms that have been released into wild populations worldwide. Hence, no experience has been gained so far with the risk assessment of LMOs containing engineered gene drives. However, several authors have discussed risk assessment aspects relevant specifically for the release of synthetic gene drives (see e.g. Benedict et al. 2008, Roberts et al. 2017, Meghani & Kuzma 2018, Hayes et al. 2018). In Australia and in the EU the regulatory authorities have started technical reviews to scrutinize current ERA frameworks with respect to their potential need for adaptation for gene drive organisms (Australian Government 2016, EC 2018). The need for a regulatory reform of corresponding regulations in the US has also been highlighted (Oye et al. 2014).

A form of "natural" gene drive, based on the intracellular bacteria *Wolbachia*, has been used to develop resistance strategies of *Aedes aegypti* to infection by human pathogenic viruses (Hoffmann et al. 2011). The aim is to render mosquitoes incapable of becoming infected by human pathogenic viruses, such as the Dengue virus. Release of *Wolbachia*-infected mosquitoes has been tested in a small number of locations around the world. In this context, risk assessment has



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been conducted for the release in Australia (Murphy et al. 2010) and Indonesia (Buchori et al. 2017).

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

The environmental risk assessment of gene drive applications will be of overarching importance when releasing engineered gene drives. Risks to human and animal health as well as to the environment need to be assessed before these novel approaches are used for release into the environment. The different approaches and methodologies to achieve gene drive require that the potential risks need to be addressed on a case-by-case basis, considering the specific methodology to construct the drive, the specific genotypic and phenotypic alterations and the characteristics of the receiving environment where the gene drive organisms are released. A particular challenge for the ERA is the stepwise approach for the testing of organisms with gene drive. Strict control and risk mitigation measures will be necessary in order to prevent accidental escape during the phased testing. Compared to conventional GMOs, the potential risks of organisms with gene drive may differ in magnitude and permanence due to the long-term and large-scale character of gene drive applications. Due to the high level of uncertainty in the assessment of the likelihood of the occurrence of adverse effects and their consequences, the resulting risk estimations may be highly speculative. In particular long term effects on whole populations or ecosystems including potential evolutionary changes in target and non-target populations are difficult to model in the ERA and are extremely unpredictable which poses a specific challenge for the risk assessment of gene drive organisms.

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

The testing and release of organisms with engineered gene drive will certainly require adaptation of current risk assessment schemes. It has to be scrutinized whether the current regulatory oversight for laboratory testing is fit for purpose if such organisms are tested under containment. For environmental release systematic scientific approaches, structured hazard analysis tools and improved predictive modelling are required to specify and evaluate long-term and large-scale risks (see also Hayes et al. 2018). Decisions on acceptable risks can only made if enough data are available to assess the specific risk. In addition, clear de-

cision criteria are required for the determination of the acceptability of such risks. Last but not least more emphasis than for conventional GMOs needs to be put on post-release monitoring, based on the results of the risk assessment, to enable timely detection of adverse effects on the environment.

**Literature cited:**


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We are looking forward to participating in the next steps concerning this highly important topic.

Thank you and kind regards

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