Submission of information requested in decision CP-9/13 on risk assessment  
and risk management of living modified organisms

**Response to CBD notification ntf-2019-009 (Reference: SCBD/CPU/DC/MA/MW/87798)**

**Submission by GERMANY**

This submission is meant to complement the submission of the European Union on notification ntf-2019-009. Please find enclosed details on the experiences, challenges and specific needs identified in Germany with regard to the risk assessment of living modified organisms containing engineered gene drives and living modified fish.

1. 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

*Living modified organisms containing engineered gene drives:*

Germany has not yet received any applications for the deliberate release of a genetically modified organism (GMO) containing an engineered gene drive.

In its position statement on gene drive systems (2016) the German Central Committee on Biological Safety (ZKBS) states that a risk assessment is always required. As a precautionary measure to counterbalance potential environmental risks that an accidental escape of a gene drive system from a genetic engineering facility might pose, the production and handling of such systems should be subject to containment level 2 unless the mandatory case-by-case assessment justifies a different containment level.[[1]](#footnote-1)

Regarding contained use, an experiment with *Drosophila melanogaster* containing a population suppression gene drive was performed in 2017[[2]](#footnote-2).

*Living modified fish:*

Germany has not yet received any applications for the deliberate release of genetically modified fish. In addition, no applications for the placing on the market of genetically modified fish have been made at EU level. Therefore, practical experience in the risk assessment of living modified fish is limited so far.

In June 2011, the ZKBS published a preliminary assessment of the available documents regarding an application by the company Aqua Bounty Technologies for approval of genetically modified salmon (brand name AquAdvantage) in the U.S. with respect to potential environmental risks[[3]](#footnote-3).

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

*Living modified organisms containing engineered gene drives:*

Germany has not yet received any applications for the deliberate release of a genetically modified organism containing an engineered gene drive. However, based on extensive practical experience in risk assessments of deliberate releases of LMO into the environment, certain specific challenges are recognised:

So far, using classical genetic engineering, modifications have mainly been introduced into domesticated species and therefore into populations managed by humans (crops, livestock, microorganisms in contained use). An escape of the modified gene into wild populations has usually been considered as an undesirable event and therefore measures were taken to minimise spread of the genetic modification. The very idea of a gene drive, however, is the spread of a genetic modification in a population belonging to a wild species and it is, in this respect, substantially different to classical LMO applications.

However, the general instruments of risk assessment as laid down in the EU legislation are applicable for these cases too, but with respect to the assessment of potential adverse effects on the environment, we expect that data requirements need to be increased on a case-by-case basis, according to an increased interaction with unmanaged ecosystems.

With respect to a stepwise approach towards the deliberate release, LMO containing engineered gene drives may pose special challenges. Depending on the characteristics of the gene drive in question, it may be difficult to perform experimental releases that are limited in time and space. This may result in reduced experimental information on the performance of a gene drive system in the environment prior to a deliberate release or placing on the market.

*Living modified fish:*

Data requirements for risk assessments of LM fish shall be determined on a case-by-case basis, depending mainly on the fish species, the safety or containment measures (if applicable), the genetic modification and the receiving environment.

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

In addition to the receiving species and the transferred gene construct, the receiving environment has to be considered in any environmental risk assessment for LMOs. For gene drives, the targeted population and its role in the functioning of the ecosystem are important determinants of the environmental risk. Therefore, the amount of information on the target population required for an adequate risk assessment will generally exceed the requirements for LMOs lacking a gene drive. Information on population genetics and dynamics, the diversity at the target locus, spatial structure of the population and subpopulations, and gene flow within and across populations will, among others, be important to assess potential effects of a release.

In general, it is to be assumed that gene drives acting in populations of wild species interact more with unmanaged ecosystems than LMOs of domesticated species. Therefore, an increased amount of information on these ecosystem interactions and potential effects on ecosystem services is expected to be required on a case by case basis.

Since complex genetic and environmental interactions dictate possible effects of a release and confined releases might often be difficult, mathematical models will probably play an increasing role during risk assessment.

1. Position statement of the ZKBS on the classification of genetic engineering operations for the production and use of higher organisms using recombinant gene drive systems; Az. 45310.0111, February 2016.

   <https://www.zkbs-online.de/ZKBS/SharedDocs/Downloads/02_Allgemeine_Stellungnahmen_englisch/01_general_subjects/Recombinant%20gene%20drive%20systems%20(2016).pdf?__blob=publicationFile&v=3> [↑](#footnote-ref-1)
2. KaramiNejadRanjbar M, Eckermann KN, Ahmed HMM, Sánchez C HM, Dippel S, Marshall JM, Wimmer EA (2018). Consequences of resistance evolution in a Cas9-based sex-conversion suppression gene drive for insect pest management. Proc Natl Acad Sci U S A. pii: 201713825. <https://www.pnas.org/content/115/24/6189.long> [↑](#footnote-ref-2)
3. ZKBS (2011) Preliminary assessment of the ZKBS of the available documents regarding an application by the company Aqua Bounty Technologies for approval of genetically modified salmon (brand name *AquAdvantage*) in the U.S. in respect of potential environmental risks

   <https://www.zkbs-online.de/ZKBS/SharedDocs/Downloads/02_Allgemeine_Stellungnahmen_englisch/07_animals/AquAdvantage%20Salmon%20(2011).pdf?__blob=publicationFile&v=2> [↑](#footnote-ref-3)