**Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety: submission of information**

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| **Country name:** | **SOUTH AFRICA** |

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;

**Gene drive:**

South Africa has not yet reviewed or undertaken a risk assessment on an actual application of living modified organisms containing engineered gene drives. However, in 2017 SA participated in the first consultative meeting on regulatory capacity building in Southern Africa on gene drive took which took place from 25 to 28 June at Gaborone, Botswana. The meeting considered following case studies of gene drivers for malaria control:

Population modification through:

* and development
* Disrupting a native gene to inhibit Plasmodium infection

Population suppression through:

* A novel gene to skew the sex ratio to produce all male offspring
* Disruption of a native gene to inhibit female fecundity

Take home messages amongst others was hence the current environmental risk assessments guidance can be used as a framework for risk assessment of gene drive applications. However, it is worth noting that there are distinguishing features of gene-drive modified organisms that could increase the overall complexity of the assessment, and so more research, both in the laboratory and in confined field trials, may also be needed. Through the experience gathered at the above mention workshop there is need to develop species- or genera-specific risk analysis frameworks.

**LM fish:**

SA has developed a national guidance document on “Risk analysis for contained use research and development activities with GM aquatic organisms”. South Africa, has practical experience in contained use risk assessments, including design and registration of several GM aquatic facilities. It is worth noting that lliving modified fish are being produced for a variety of purposes, including growth-enhancement, infection resistance or cold tolerance and some have already reached commercial production stage. There are potential risks linked to LM fish, including impact on wild species resulting from intentional release or escape into the natural environment. Therefore the base work that has already undertaken to develop the broad framework for GM fish may provide sufficient basis for further guidance to be developed.

It is worth noting that the National Environmental Biodiversity Act 10 of 2004 makes provision for an Environmental Impact Assessment (EIA) to be conducted for GMOs intended for release into the environment which may pose a threat to any indigenous species or the environment. As such, South Africa’s Environmental Risk Assessment Framework Guidance Document for GMOs developed in 2008 provides a non-exhaustive list of possible triggers of an EIA, which includes GMOs with the potential to become invasive, such as GM fish.

**Additional:**

There are number of research being undertaken on genetically engineered animals (GEMS), some as a result of crispr-cas technology (mice and rats only). These strains are mainly used in drug development or nutrition studies and are imported under permit from DAFF. They are housed in a contained facility with limited access control and most will not survive outside of the specialized conditions that they are kept. They also breed such animals for other research centres or groups. The only foreseeable risk factor is that animals may escape if there is a serious accident during transport of the animals. The animals are contained in specialized transport cages and it will take a strong force to break open the cages though. The academic institution involved in this work intends on generating our own genetically engineered strains.

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

None related to the risk analysis framework itself, but due to the designed pervasiveness of gene drives a more geographically-integrated approach may be required, including regional (multilateral) assessments and decision making when relevant. It is worth noting that experiences gained with GM crop risk analyses may be broadly applicable to and valuable when assessing other organisms, such as fish, as well.

How benefits are weighed against risks is critical for evaluating gene drive technologies in South Africa’s context. The South African regulatory system considers the weighing up of benefits in the decision making process. How benefits and risks are weighed up will be more important when the desired outcome is the reduction/ local extinction of a species with associated ecological impacts.

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

* As mentioned above this may require regional forums, for both discussion and approval.
* Weighing up benefits vs risks (mentioned above)