

## **Information on risk assessment of LMOs containing engineered gene drives and LM fish**

In the notification No 2019-009, Parties are invited to submit information related to:

- 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;
- b) Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish;
- c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

### Information concerning organisms containing engineered gene drives

As regards organisms containing engineered gene drives, there is no direct experience in undertaking risk assessment in the Czech Republic as there are no experiments with such organisms, neither in contained use nor deliberate release into the environment. Up to now, even no application for the authorisation of these experiments has been submitted in the Czech Republic.

Nevertheless, we consider "gene drives technology" potentially harmful to the conservation and sustainable use of biodiversity as this technology alters genomes in ways that would result in irreversible spreading and persistence a trait throughout a population. Therefore we are of the opinion that any experiments with organisms containing gene drives should be carried out under biosafety level 3.

### Information concerning risk assessment of LM fish in the Czech Republic

The Czech GMOs Act No 78/2004 and implementing Decree 209/2004 transpose two EU Directives 2001/18/EC and 2009/41/EC, covering thus all three types of GMO use: 1) the contained use, 2) deliberate release into the environment for any other purpose than placing on the market and 3) placing on the market of GMOs as or in products.

Risk assessment (incl. LM fish) is carried out pursuant § 7 of the Act and § 5 of the Decree. In addition, Annex 4 of the Decree determines specific requirements for containment - work area and protective measures defined for resulting biosafety level, part C of the Annex 4 specifically determines requirements for the containments and protective measures for animal facilities, incl. fish.

Currently there are 3 research institutions and 1 university authorised to carry out experiments with LM fish under the contained use regime in the Czech Republic. GM *Danio rerio* and *Cyprinus carpio* are subjects of experiments. So far, all risk assessments that have been carried out resulted in their classification into biosafety level 1. Up to now, no application for deliberate release into the environment has been submitted in the Czech Republic.