

EFSA discusses risk assessment of gene drives

Testbiotech demands that 'cut-off' criteria are applied

30 April 2020 / The European Food Safety Authority (EFSA) carried out a public consultation on guidance for the risk assessment of so-called gene drives at the request of the EU Commission. At the same time, a new Testbiotech scientific paper was accepted after peer review. The paper shows that the EFSA concept is insufficient. To control the risks of gene drives, 'cut-off criteria' need to be defined to prevent the uncontrolled spread of genetically engineered organisms.

Gene drives are genetic elements which can spread much more widely than would normally be expected. In recent years, artificial gene constructs have been developed using the gene scissor CRISPR/Cas. Organisms, inheriting such gene constructs, are meant to be released and intended to spread rapidly, especially throughout wild populations. The goal is to replace or eradicate the targeted species. However, once started, the spread can no longer be effectively controlled. Damage to human health and the environment can be extensive.

Against this backdrop, EFSA is currently working on guidance for the risk assessment of mosquitoes which inherit genetically engineered gene drives. There are already proposals to use these mosquitoes to fight malaria in Africa: the plan is to eradicate those species which can transmit malaria via a mutagenic chain reaction, or replace them with mosquitoes that can no longer be a vector of the disease.

As the new Testbiotech publication shows, this poses a substantial problem in risk assessment: to be successful, the genetic construct has to be inherited by dozens of generations and billions of mosquitoes. This process would take place in the natural environment outside of the laboratories, over longer periods of time, without effective control mechanisms being available. During this process, the genetically engineered mosquitoes and their offspring would be exposed to an unlimited number of genetic factors and environmental impacts. Therefore, the outcome of any release of genetically engineered mosquitoes can massively deviate from what was originally expected.

There is no sufficiently reliable method to predict the biological effects in the offspring of the genetically engineered mosquitoes. The risks include a higher risk of disease transmission, triggering allergenic reactions due to mosquito bites or severe disruption in ecosystems.

These risks are indeed acknowledged in the text provided by EFSA for the public consultation. However, EFSA does not mention that the precautionary principle must be applied: the EU only allows the release of genetically engineered organisms if they have been demonstrated to be safe, and if they can be retrieved from the environment where an urgent need arises. Neither of these conditions are met in the case of genetically engineered gene drive mosquitoes. Against this backdrop, Testbiotech is demanding substantial amendments to the EFSA draft.

If gene drive organisms cannot be controlled in space and time, then risk assessment cannot come to sufficiently reliable conclusions. Releases cannot be allowed under such conditions. The Testbiotech recommendation is further based on the results of the GeneTip research project which published its final findings this week.

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Further information: [The new peer-reviewed Testbiotech paper](#) [2]

[The GeneTip results: „Gene Drives at Tipping Points“ \(open access\)](#) [3]

[The EFSA document published for public consultation](#) [4]

[Testbiotech video clip on the risks of gene drive mosquitoes \(german language with english subtitle\)](#)

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Links

[1] <mailto:info@testbiotech.org>

[2] <https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4278>

[3] <https://link.springer.com/book/10.1007/978-3-030-38934-5>

[4] <http://www.efsa.europa.eu/en/consultations/call/public-consultation-gmo-panel-scientific-opinion-evaluation>

[5] <https://www.testbiotech.org/en/node/2365>