

## <u>Press statement by Save Our Seeds on EFSAs advise for the risk assessment of Gene Drive Insects</u>

13.11.2020

The European Food Safety Agency (EFSA), on 12.11.2020 published an assessment on whether the currently existing European guidelines for the risk assessment of genetically modified insects are sufficient for the risk assessment of genetically modified Gene Drive insects.

Mareike Imken, Gene Drive policy advisor at Save Our Seeds for Gene Drive technology, comments on this:

"EFSAs assessment, that existing guidelines for genetically engineered insects are insufficient in order to conduct environmental risk assessment for Gene Drive Organisms, confirms our analysis: Due to their novel characteristics it will be extremely challenging – if not impossible – to model, predict and monitor the behaviour of these genetically engineered organisms.

However, EFSA does not acknowledge a key challenge for the risk assessment and monitoring of genetically engineered Gene Drive Organisms – so called next-generation-effects – due to their choice of comparators which lack the key characteristic of uncontrollable cross-generation genetic engineering.

Next generation effects would encompass unintended changes to the biological characteristics in the offspring of Gene Drive Organisms, that will likely happen due to the repeated and uncontrollable process of genetic engineering that Gene Drives set in motion in nature. When the repeated process of genetic engineering cannot be controlled in space and time – as is the case with genetically engineered Gene Drive Organisms – its effects cannot be predicted by risk assessment.

The likely impossibility to model and predict next-generation-effects, as already observed with the offspring of genetically engineered plants, calls for the establishment of cut-off-criteria for risk assessment. They would apply when predictions cannot be made due to uncertainty and limits of knowledge. In this case risk assessment would have to be interrupted and authorization could not be granted.

Apart from that we should not forget that decision-making about this technology needs to be informed by more than risk assessment: There is an urgent need for a broader political debate and processes for participatory, inclusive and democratic societal deliberation around the desirability, costs and benefits of this technology in comparison to alternative solutions as well as its compatibility with societal values and ethics as a base for political decision-making around gene drive technology."

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