Gene Drives

A report on their science, applications, social aspects, ethics and regulation

Summary

Gene drives are a new form of genetic modification that permanentely alter or even eradicate species or populations in the wild. In contrast to 'conventional' GMOs, they are meant to spread and persist in nature; or in other words: they are meant to be invasive.

Many different forms of engineered gene drives are being suggested and developed. Chapter 1 is detailing those, helping to understand the actions, risks and limitations of each of them.

Target species include insects, small mamals, fish, birds, plants, mollusks, nematodes, flatworms and fungi, including yeasts. Chapter 2 lists them with information about their geographic range, the problem that they aim to address, the readiness of the respective technologies, institutions and funders, and more.

Gene Drive Organisms (GDOs) carry serious additional risks compared to GMOs. These relate to questions of diverse natural conditions, high genetic variation of the target species in wild populations, and a myriad of interactions with other species in complex systems. The risk assessment of GDOs has to be done on the basis of organisms and ecosystems, instead of starting from the premises of desired benefits.

A range of open issues is therefore discussed in three case studies: mosquitoes, mice and Palmer amaranth, a plant, also used as food, that has become a weed of significant proportions since the introduction of herbicide-tolerant GM crops.

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Even CRISPR/Cas-based gene drives (Chapter 1), that are currently the technically most advanced gene drives, are not fit for application because of serious limitations of their functioning and because of important uncertainties at scientific, technical and practical levels. Most of these have so far only been addressed in theoretical models.

As detailed in Chapter 2, there is no solid scientific basis for performing the adequate

and robust risk assessment that is essential to safeguard biodiversity as well as human health. Given the high level of unpredictability, the lack of knowledge and the potentially severe negative impacts on biodiversity, ecosystems and agroecosystems, any release of GDOs has to be placed on hold.
This has to include the experimental release of GDOs. In the current situation, applying the Precautionary Principle is the best guide when facing this new and potent technology.

Military funding is currently one of the largest resources for gene drive research, indicating that gene drives are considered as offensive or defensive weapons. Due to their inherent and intended nature of modifying or eradicating species or populations, gene-drives are a dual-use technology, so gene drive R&D for civilian and military purposes cannot be separated.

A precautionary approach is also needed for social issues around GDOs as outlined in Chapter 3. Acknowledging uncertainty is the bust guarantee for effective and efficient innovations that respect human health, the environment and biodiversity.

But, as discussed in Chapter 3 and 4, considerations about gene drives must not be restricted to technical assessments of feasibility and risks. Being a "technological fix" gene drives avert from alternative ways of framing and solving the problems the technology is claimed to address. A more holistic approach including local experience may prove more sustainable in the long run.

Therefore public engagement has to take place at the very beginning of the process, when funders, innovation stakeholders and researchers define what a problem is and set R&D priorities. In the light of the many uncertainties of the "technological fix" free prior informed consent of the population affected is indispensable. In this context "information" must not be reduced to advertising (see also Chapter 5).

Chapter 5 explains the urgent need for effective international and legally binding regulation of GDOs. Existing biosafety rules are established for 'conventional' GMOs and therefore not fully equipped to manage the additional and unique risks of GDOs. The scope of the *Convention on Biological Diversity* (CBD) and its Protocols includes GDOs and its bodies have begun substantive work on the issue. Therefore the CBD is currently the best home for the international governance of GDOs.

Legally binding governance arrangement need to be put in place at an international level, but are not there yet. Therefore, in the interim, there should be no intentional releases into the environment of GDOs. This must include field trials as well. Strict contained use standards need to be applied to existing laboratory research. Monitoring and detection for unintentional releases and unintentional transboundary movements of GDOs have to be conducted, and international rules for this period of constraint must be effectively operational, including at national levels.

The five chapters of the report are written by Ricarda A. Steinbrecher, Mark Wells, Ruthi Brandt, Elisabeth Bücking, Doug Gurian-Sherman, Tamara Lebrecht, Helen Wallace, Irina Castro, Christopher Preston, Fern Wickson, Lim Li Ching and Lim Li Lin.